Study Protocol Clinical Trial

Medicine®

OPEN

Effect of LED therapy for the treatment nipple fissures

Study protocol for a randomized controlled trial

Thalita Molinos Campos, DDS[a,*], Maria Aparecida dos Santos Traverzim, MSc[a], Ana Paula Taboada Sobral, MSc[a], Sandra Kalil Bussadori, PhD[a], Kristianne Santos Porta Fernandes, PhD[a], Lara Jansiski Motta, PhD[a], Sergio Makabe, PhD[b]

Abstract

Introduction: Poor positioning of the child in relation to the breast and improper suckling are the main causes of nipple fissure. Treatment options for nipple fissures include drug therapy with antifungal and antibiotics, topical applications of lanolin, glycerin gel, creams and lotions, the milk itself, hot compresses, and silicone nipple shields. Studies involving light-emitting diode (LED) therapy have demonstrated anti-inflammatory properties, the enhancement of the wound repair process, and the control of pain. As it does not cause discomfort, is relatively inexpensive and may impede the discontinuation of breastfeeding, phototherapy could be a viable option for the treatment of nipple fissures.

Aim: The principal objective of the proposed study is to evaluate the effectiveness of LED therapy for the treatment of nipple fissures in postpartum mothers.

Materials and methods: One hundred patients treated with a medical diagnosis of bilateral nipple trauma classified as nipple fissures or cracks will participate in the study, randomized into 2 groups: The control group will receive orientation regarding breast care and adequate breastfeeding techniques. The experimental group will receive the same orientation and phototherapy sessions using a device developed especially for the treatment of nipple trauma. Both groups will be followed up for 6 consecutive weeks.

Abbreviations: LASER = light amplification by stimulated emission of radiation, LED = light-emitting diode, SPIRIT = Standard Protocol Items for Randomized Trials, UNICEF = United Nations Children's Fund, VAS = visual analog scale, WHO = World Health Organization.

Keywords: breastfeeding, healing, mammary diseases, phototherapy, quality of life

1. Introduction

During pregnancy and in the postpartum period, care is fundamental to minimizing problems, such as nipple trauma[1] due to the occurrence of fissures associated with an inflammatory process of the upper layer of the dermis.[2] Around 98% of women can physiologically breastfeed, but many mothers avoid this practice. Nipple fissures are the second major cause of the discontinuation of breastfeeding, followed by the sensation of insufficient milk that many mothers have, leading to the habit of bottle feeding.[3] Nipple fissures are classified as either circular or longitudinal and vary in size. A circular fissure is commonly located at the nipple-areolar junction, whereas a longitudinal fissure is situated throughout the entire length of the nipple either vertically or horizontally, dividing it into 2 halves.[4]

Nipple fissures tend to appear in the second or third week of the postpartum period and are a frequent cause of pain that often leads to premature discontinuation of breastfeeding.[2] Poor positioning of the child in relation to the breast, an inadequate frequency or duration of breastfeeding, and improper suckling are the main causes of nipple fissure.[1] Since 1991, both the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have dedicated international efforts to protecting, promoting, and supporting exclusive breastfeeding until an infant reaches 6 months of age.[5]

The discontinuation of breastfeeding deprives an infant of the essential nutrients, growth factors, and important immunological components in breast milk. For the mother, not breastfeeding hinders uterine involution, increases the risk of postpartum hemorrhage, and increases the risk of ovarian and breast cancer, not to mention the affective aspect of the mother–child bond that is created through the breastfeeding experience.[6]

Treatment options for nipple fissures include drug therapy with antifungal agents and antibiotics, topical applications of lanolin, glycerin gel, creams and lotions, the milk itself, hot compresses, silicone nipple shields, and phototherapy.[7,8] It should be stressed that nipple fissures can be a gateway for bacteria, which could lead to more serious conditions, such as abscess and mastitis.[9,10]

Phototherapy is the use of electromagnetic waves within the red and infrared spectra that are applied to biological tissues with the aid of low-level light devices, such as light amplification by stimulated emission of radiation (laser) and a light-emitting diode (LED). Studies have demonstrated the anti-inflammatory

The authors report no conflicts of interest.

[a] Postgraduate Program in Biophotonics Applied to Health Sciences, Universidade Nove de Julho, UNINOVE, [b] Hospital Mandaqui, São Paulo, Brazil.

[*] Correspondence: Thalita Molinos Campos, Postgraduate Program in Biophotonics Applied to Health Sciences, Universidade Nove de Julho, UNINOVE, Rua Vergueiro, 235/249 Liberdade, São Paulo – SP 01504-000, Brazil (e-mail: thalita.molinos@gmail.com).

Medicine (2018) 97:41(e12322)

Received: 16 August 2018 / Accepted: 21 August 2018

http://dx.doi.org/10.1097/MD.0000000000012322

properties of phototherapy, with the enhancement of the wound repair process[11–13] and the control of pain.[14,15] As it does not cause discomfort, is relatively inexpensive, and may impede the discontinuation of breastfeeding, phototherapy could be a viable option for the treatment of nipple fissures.[16]

2. Methods/Design

The principal objective of the proposed study is to evaluate the effectiveness of LED therapy for the treatment of nipple fissures in postpartum mothers. The secondary objectives are to evaluate the effect of LED therapy on the healing of nipple fissures in postpartum mothers; evaluate the effect of LED therapy on the control of pain during breastfeeding in postpartum mothers with nipple fissures; and evaluate the impact of the treatment of nipple fissures with LED therapy on the quality of life of postpartum mothers.

This protocol follows the SPIRIT (Standard Protocol Items for Randomized Trials) recommendations displayed in Fig. 1 and Table 1.

2.1. Methods

A controlled clinical trial will be conducted to evaluate the effects of LED therapy on tissue healing, pain, and quality of life in postpartum mothers with nipple fissures. One hundred patients treated at the Mandaqui Hospital in the city of São Paulo, Brazil, with a medical diagnosis of bilateral nipple trauma classified as nipple fissures or cracks will participate in the study. All patients must sign an informed consent form.

All participants will answer a questionnaire addressing basis information (age, gestation time, and infant's age) and history of nipple fissures, will indicate their pain at baseline using the Visual Analog Scale (VAS), and will answer a quality-of-life questionnaire. All participants will sign a statement of informed consent before the onset of the study.

2.2. Eligibility criteria

The following will be the inclusion criteria:

(1) Nursing mothers aged 18 years or older;
(2) Diagnosis of nipple fissure and nipple pain with a minimum score of 1 on the Store and Champion scales;
(3) Having given birth to a healthy, full-term child;
(4) Performing exclusive breastfeeding;
(5) Newborn with no oral, palatal or maxillofacial abnormalities;
(6) Newborn weighing between 2500 and 4000 g.

The following will be the exclusion criteria:

(1) History of psychological disorder;
(2) Presence of mastitis;
(3) Bacterial or fungal infection in breasts;
(4) Use of breast pump or plastic nipple.

The participants will be randomly allocated to either the experimental or control group using a randomization site (http://www.randomization.com). The control group will receive orientation regarding breast care and adequate breastfeeding techniques. The experimental group will receive the same orientation and phototherapy sessions using a device developed especially for the treatment of nipple trauma. Both groups will be followed up for 6 consecutive weeks. The information will be registered in an Excel Program.

The patients will be submitted to an initial evaluation by an examiner blinded to the group allocation. The aim of the evaluation will be to characterize the participant (age, skin color, number of children, schooling, type of birth, previous breastfeeding experience, and time of puerperium) and the nipple [color and type (protruded, semi-protruded, inverted, or hypertrophic)]. After the evaluation, the participants will be sent to begin the interventions.

The patient will be instructed not to use creams, soaps, or any type of ointment on the nipples, to wear bras with wide, firm straps to support the breasts, to remain in a comfortable position during breastfeeding with the infant's body turned completely toward the mother. Secure the breast in a C shape to facilitate the infant's latching, wait for the infant to empty the first breast offered completely before moving to the other breast, and place the tip of the little finger in the corner of the infant's mouth to facilitate its removal from the breast. This information will be given to the women at the initial evaluation as well as in the third and sixth weeks always by the same researcher in both oral and printed (educational brochure) form.[16]

The strategy to adherence to the intervention protocol will be information about nipple fissures and complications. All participants, regardless of group, will be part of a support group for the mother and baby with educational activities and care.

2.3. Ethical aspects

This study received approval from the human research ethics committee (certificate number: 2.540.438) and is registered with ClinicalTrials (number: NCT03496753).

2.4. Intervention

2.4.1. Phototherapy - LED. The following will be the phototherapeutic parameters: total spot area: 1.44 cm^2; continuous emission mode; output power: 10 mW; infrared wavelength (880–904 nm); fluence: 4 J/cm^2; and application time: 10 minutes/session. Sessions will be held 3 times a week on alternating days for 6 consecutive weeks, totaling 18 sessions.

2.4.2. Clinical parameters for evaluation of fissures. Nipple fissures will be measured in the first, third, sixth, ninth, 12th, 15th, and 18th sessions using digital calipers (Black Bull) and classified at the beginning and end of the study based on Pereira et al [17]: small ($\leq$ 3 mm), medium ($>$ 3 and $\leq$ 6 mm), or large ($>$ 6 mm).

2.4.3. Pain scale. Pain will be measured using the Visual Analog Scale in the first, fourth, seventh, 10th, 14th, and 17th sessions by a single researcher. In the experimental group, pain will be measured before the administration of phototherapy.

2.4.4. Quality of life. The impact of nipple fissures on the quality of life of the participants will be evaluated using the self-administered EQ-5D questionnaire in the third and sixth weeks of the study. The EQ-5D is a generic health-related quality-of-life assessment tool developed in Europe that has been translated and validated in different languages, including Portuguese.[17]

2.5. Outcomes

The main outcomes of the study will be the treatment of nipple fissures and a reduction in nipple pain. The secondary outcomes will be related to the quality of life of the participants.

Study Period																				
	Enrolment	Allocation	Post-allocation																	
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_{11}	t_{12}	t_{13}	t_{14}	t_{15}	t_{16}	t_{17}	t_{18}
ENROLMENT:	x																			
Eligibility screen	X																			
Informed consent	X																			
[List other procedures]	X																			
Allocation		X																		
INTERVENTIONS:																				
[LED]																				
[Orientation]			X								X							X		
ASSESSMENTS:																				
[nipple trauma]	X		X		X			X			X			X			X			X
[quality of life]											X									X
[pain]			X			X			X			X				X			X	

*t_1 -1st session
*t_2- 2nd session
*t_3- 3rd session
*t_4 -4th session
*t_5 -5th session
*t_6 - 6th session
*t_7 - 7th session
*t_8 - 8th session
*t_9 - 9th session
*t_{10} – 10th session
*t_{11} – 11th session
*t_{12} – 12th session
*t_{13} – 13th session
*t_{14}- 14th session
*t_{15}- 15th session
*t_{16}- 16th session
*t_{17}- 17th session
*t_{18}- 18th session

Figure 1. Schedule of enrolment, interventions, and assessments of the study.

2.6. Sample size

The sample size was calculated based on the results of previous studies[18] and considering a possible dropout rate of 10% to 15% throughout the follow-up period. For a 95% confidence interval, 80% test power, and $\alpha = 0.05$, it was determined that 50 women would be needed for each group (total: 100 participants).

2.7. Statistical analysis

The statistical analysis will be performed with the aid of SPSS 20.0 (IBM Corporation, Armonk, NY). The Kolmogorov–Smirnov test will be used to determine the normality of the data. Depending on the distribution, the data will be expressed as mean and standard deviation for continuous variables. Repeated-

Table 1

SPIRIT 2013 checklist: recommended items to address in a clinical trial protocol and related documents*.

Section/item	Item no.	Description	Pag	
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	0k	01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	0k	06
	2b	All items from the World Health Organization Trial Registration Data Set	0k	06
Protocol version	3	Date and version identifier	0k	06
Funding	4	Sources and types of financial, material, and other support	0k	04
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	0k	01
	5b	Name and contact information for the trial sponsor	0k	02
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	0k	04
	5d	Composition, roles, and responsibilities of the coordinating center, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA	
Introduction				
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	0k	04
	6b	Explanation for choice of comparators	0k	05
Objectives	7	Specific objectives or hypotheses	0k	04
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	0k	04
Methods: participants, interventions, and outcomes				
Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	0k	04
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centers and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	0k	05
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	0k	06
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	0k	06
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	0k	06
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	0k	06
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	0k	07
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	0k	06
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	0k	04
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	0k	05
Methods: assignment of interventions (for controlled trials)				
Allocation				
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	0k	05
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	0k	05
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	0k	05

(*continued*)

Table 1

(continued).

Section/item	Item no.	Description	Pag	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	Ok	05
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA	
Methods: data collection, management, and analysis				
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Ok	07
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Ok	06
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Ok	05
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Ok	07
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	Ok	07
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomized analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Ok	06
Methods: Monitoring				
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Ok	04
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Ok	05
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Ok	05
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ok	06
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Ok	06
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	Ok	04
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Ok	05
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	NA	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Ok	05
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ok	05
	31b	Authorship eligibility guidelines and any intended use of professional writers	Ok	04
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA	
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	Ok	05
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA	

* It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

NA = not applicable.

measures analysis will be performed considering group and evaluation time. The Mann–Whitney test, *t* test for independent samples, and Fisher exact test will be used for the comparisons, and a P value $< .05$ will be considered indicative of statistical significance. The statistical analysis will be blinded.

3. Discussion

This article describes the protocol for a randomized, controlled, clinical trial for the evaluation of the effect of LED therapy for the treatment of nipple fissures in nursing mothers. One of the advantages of the study is the action of LED therapy in the control of nipple pain and the induction of healing of the traumatized breast tissue.[16]

Nipple fissures and pain can occur during the lactation period, especially in the initial days of breastfeeding and can even lead to premature weaning. Breast milk is nutritionally ideal for the healthy development of a child and breastfeeding is ideal for orofacial growth and development.[8,13]

Nipple pain is generally reported 3 to 6 days after giving birth and can persist for up to 6 weeks.[1] Untreated fissures can compromise the infant's nutrition and can lead to complications, such as mastitis, bleeding, infection, and abscess.[19] The treatments described in the literature include medications, natural extracts, compresses, and lanolin. However, these treatments are not effective with regard to both tissue healing and the control of pain.

Considering the importance of breastfeeding and the high prevalence of nipple fissures, this study proposes a novel way to control nipple pain and accelerate the healing process of nipple fissures through the use of LED therapy, which is a noninvasive technique with no side effects, such as the allergic reactions that can be caused by the ingestion of substances.

Author contributions

Methodology: Thalita Molinos Campos, Maria Aparecida Traverzim, Ana Paula Sobral, Sergio Makabe, Sandra Bussadori, Kristianne Fernandes, Lara Motta.
Writing – original draft: Thalita Molinos Campos, Lara Motta.
Writing – review & editing: Thalita Molinos Campos, Maria Aparecida Traverzim, Ana Paula Sobral, Sergio Makabe, Sandra Bussadori, Kristianne Fernandes, Lara Motta.

References

[1] Giugliani ERJ. Common problem during lactation and their management. J Pediatr 2004;80:147–54.
[2] Smith JW, Tully MR. Midwifery management of breastfeeding: using the evidence. J Midwifery Womens Health 2001;46:423–38.
[3] Page T, Lockwood C, Guest K. Management of nipple pain and/or trauma associated with breast-feeding. JBI Rep 2003;1: 127–47.
[4] Fonseca RP, Ferreira VJA. Relation of normal term infants sucking pression and latch with nipple fissures appearing on natural feeding process. Rev CEFAC 2004;6:49–57.
[5] Tait P. Nipple pain in breastfeeding women: causes, treatment, and prevention strategies. J Midwifery Womens Health 2000;45: 212–5.
[6] Brasil. Ministério da Saúde. Secretaria de Atenção à Saude. Tips for child well-being. Brasília: Ministério da Saúde/Biblioteca Virtual em Saúde do Ministério da Saúde; 2008.
[7] Dennis CL, Jackson K, Watson J. Interventions for treating painful nipples among breastfeeding women. Cochrane Database Syst Rev 2014; CD007366.
[8] Sayyah Melli M, Rashidi MR, Delazar A, et al. Effect of peppermint water on prevention of nipple cracks in lactating primiparous women: a randomized controlled trial. Int Breastfeed J 2007;2:7.
[9] Fetherston C. Risk factors for lactation mastitis. J Hum Lact 1998; 14:101–9.
[10] Riordan JM, Nichols FHA. Descriptive study of lactation mastitis in long-term breastfeeding women. J Hum Lact 1990;6:53–8.
[11] Gonçalves RV, Novaes RD, Matta SL, et al. Comparative study of the effects of gallium- -aluminum- arsenide laser photobiomodulation and healing oil on skin wounds in Wistar rats: a histomorphometric study. Photmed Laser Surg 2010;28:597–602.
[12] Dadpay M, Sharifian Z, Bayat M, et al. Effects of pulsed infrared low level-laser irradiation on open skin wound healing of healthy and streptozotocin induced diabetic rats by biomechanical evaluation. J Photochem Photobiol B 2012;111:1–8.
[13] Fiório FB, Silveira LJr, Munin E, et al. Effect of incoherent LED radiation on third-degree burning wounds in rats. J Cosmet Laser Ther 2011;13: 315–22.
[14] Chung H, Dai T, Sharma SK, et al. The nuts and bolts of low-level laser (light) therapy. Ann Biomed Eng 2012;40:516–33.
[15] Cauwels RG, Martens LC. Low level laser therapy in oral mucositis: a pilot study. Eur Arch Paediatr Dent 2011;12:118–23.
[16] Araujo AR, Nascimento ALV, Camargos JM, et al. Photobiomodulation as a new approach for the treatment of nipple traumas: a pilot study, randomized and controlled. Fisioter Bras 2013;14: 20–6.
[17] Ferreira PL, Ferreira LN, Pereira LN. Contribution for the validation of the Portuguese version of EQ-5D. Acta Med Port 2013; 26:664–75.
[18] Marrazzu A, Sanna MG, Dessole F, et al. Evaluation of the effectiveness of a silver-impregnated medical cap for topical treatment of nipple fissure of breastfeeding mothers. Breastfeed Med 2015;10: 232–8.
[19] Pereira MJB, Reis MCG, Shimo AKK, et al. Manual de procedimentos: prevenção e tratamento das intercorrências mamárias na amamentação. Programa Aleitamento Materno – SMS (Secretaria Municipal da Saude), NALMA (Nucleo de Aleitamento Materno da EERP-USP). SUS. Ribeirão Preto; 1998.