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Author(s)	Nakamura, Maya; Luo, Yunjie; Ebina, Yasuhiko
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BMJ Open Effectiveness of moisturising therapy in treating nipple trauma: a systematic review protocol

Maya Nakamura ¹, Yunjie Luo ², Yasuhiko Ebina ²

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¹Graduate school of Health Sciences, Hokkaido University, Sapporo, Hokkaido, Japan

²Faculty of Health Sciences, Hokkaido University, Sapporo, Hokkaido, Japan

Correspondence to

Maya Nakamura;
m_nakamura@hs.hokudai.ac.jp

ABSTRACT

Introduction Breastfeeding is crucial in infant nutrition and bonding, recommended for at least 6 months and up to 2 years postpartum, providing health benefits for both infants and mothers. However, nipple trauma is common among lactating mothers. Moisturising therapies, such as hydrogel application, aim to promote the healing of nipple wounds. Despite various interventions proposed, comprehensive reviews evaluating the efficacy of moisturising therapies for nipple trauma are lacking. This review aims to appraise the effectiveness of moisturising therapy, particularly tailored for nipple trauma in lactating women.

Methods and analysis This systematic review protocol adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines and is registered in the International Prospective Register of Systematic Reviews. The focus will be on both randomised and non-randomised controlled trials addressing the treatment of nipple trauma in lactating women. In this context, 'moisturising therapy' is categorised as a non-pharmacological intervention applied directly to the nipple, excluding treatments for bacterial or fungal infections. The primary outcomes will include measures of the healing efficiency of nipple trauma and reduction in nipple pain. Searches will be conducted without date restrictions across multiple databases, including PubMed, CINAHL, the Cochrane Library, Web of Science, CiNii Research and Ichushi-Web, in addition to exploration of grey literature. Two independent reviewers will manage all stages of the review process, under the supervision of a third reviewer. Data extraction will encompass participant demographics, study methodologies, sample specifics and measured outcomes. Quality assessment will be conducted using the Joanna Briggs Institute Appraisal Checklist Tools.

Ethics and dissemination Ethics approval is not required for this study. The findings of this review will be disseminated through academic publications, detailed reports and presentations at relevant conferences.

PROSPERO registration number CRD42023481761.

INTRODUCTION

Breastfeeding is fundamental to infant nutrition and emotional bonding, endorsed for at least the initial 6 months, followed by the introduction of complementary foods. Experts typically advocate for the continuation of breastfeeding for up to 1 year, with

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This systematic review is designed to comprehensively assess various interventions for nipple trauma, with a specific focus on the efficacy of moisture-based therapies, thereby aiming to refine treatment strategies for lactating women.
- ⇒ The study will undertake an in-depth analysis of different sources of heterogeneity and independently assess the risk of bias in the included studies by two researchers, ensuring a robust and impartial evaluation.
- ⇒ This study recognises the potential for variable and suboptimal reporting quality concerning the effectiveness of treatments for nipple trauma, which may affect the conclusiveness of the findings.
- ⇒ This review will exclude databases in languages other than English or Japanese, such as French, German and Chinese. This exclusion risks introducing language bias, potentially overlooking pertinent studies and insights.

the WHO advising a minimum of 2 years.^{1 2} This practice bestows numerous health benefits, including a reduced risk of respiratory infections and diarrhoea in infants and lower incidences of breast and ovarian cancer, postpartum depression, hypertension and cardiovascular diseases in mothers.^{2 3} However, a study spanning 57 low- and middle-income countries between 2010 and 2018 reported a global weighted prevalence of only 51.9% for early initiation of breastfeeding and 32% for exclusivity at 4–5 months.⁴ Nipple trauma, affecting 80%–90% of breastfeeding mothers, significantly contributes to the onset of mastitis and is associated with heightened pain levels, leading to mental health decline and often resulting in the premature cessation of breastfeeding.^{5–8} Although various prevention and treatment strategies like corrective breastfeeding techniques, topical ointments and moist wound therapies have been proposed,^{5 7 9–11} none has been definitively superior.

The principle of moist wound healing established in the 1960s highlights the

Table 1 Initial search syntax for PubMed

#	Search syntax
1	Nipples(mh) OR nipple*(tiab)
2	injur*(tiab) OR injuries (subheading) OR trauma*(tiab) OR wound*(tiab) OR breakage*(tiab) OR crack*(tiab) OR fissure*(tiab) OR Pain (Mesh:NoExp) OR pain*(tiab) OR sore*(tiab)
3	#1 AND #2
4	therap*(tiab) OR therapy (subheading) OR treat*(tiab) OR heal*(tiab) OR care(tiab) OR cure(tiab) OR management(tiab) OR reduc*(tiab) OR repair*(tiab) OR improv*(tiab) OR Skin Care(mh) OR Pain Management(mh) OR Wound Healing(mh)
5	#3 AND #4
6	'Randomised Controlled Trial'(pt) OR 'Controlled Clinical Trial'(pt) OR 'Pragmatic Clinical Trial'(pt) OR 'Equivalence Trial'(pt) OR 'Clinical Trial, Phase III'(pt) OR 'Randomised Controlled Trials as Topic'(mh) OR 'Controlled Clinical Trials as Topic'(mh) OR 'Random Allocation' (mh) OR 'Double-Blind Method'(mh) OR 'Single-Blind Method'(mh) OR Placebos(Mesh:NoExp) OR 'Control Groups'(mh) OR (random*(tiab) OR sham(tiab) OR placebo*(tiab)) OR ((singl*(tiab) OR doubl*(tiab)) AND (blind*(tiab) OR dumm*(tiab) OR mask*(tiab))) OR ((tripl*(tiab) OR trebl*(tiab)) AND (blind*(tiab) OR dumm*(tiab) OR mask*(tiab))) OR (control*(tiab) AND (study(tiab) OR studies(tiab) OR trial*(tiab) OR group*(tiab))) OR (Nonrandom*(tiab) OR 'non random*(tiab) OR 'non-random*(tiab) OR 'quasi-random*(tiab) OR quasirandom*(tiab) OR allocated(tiab) OR (('open label'(tiab) OR 'open-label'(tiab)) AND (study(tiab) OR studies(tiab) OR trial*(tiab))) OR ((equivalence(tiab) OR superiority(tiab) OR 'non-inferiority'(tiab) OR noninferiority(tiab)) AND (study(tiab) OR studies(tiab) OR trial*(tiab))) OR ('pragmatic study'(tiab) OR 'pragmatic studies'(tiab)) OR ((pragmatic(tiab) OR practical(tiab)) AND trial*(tiab)) OR ((quasiexperimental(tiab) OR 'quasi-experimental'(tiab)) AND (study(tiab) OR studies(tiab) OR trial*(tiab))) OR (phase(ti) AND (III(ti) OR 3(ti)) AND (study(ti) OR studies(ti) OR trial*(ti))) OR (phase(ot) AND (III(ot) OR 3(ot)) AND (study(ot) OR studies(ot) OR trial*(ot)))
7	#5 AND #6

importance of maintaining optimal moisture levels to accelerate healing processes, reduce scar formation and prevent tissue dehydration.^{12–14} In the context of nipple trauma, treatments such as breast milk, lanolin and hydrogel dressings have been advocated to sustain a moist environment, thus lowering infection risks and alleviating pain.^{7 15}

Despite the variety of proposed treatments, evidence specifically assessing the effectiveness of moisturising therapies for nipple trauma remains scant. This review aims to scrutinise the efficacy of such therapies for lactating women facing nipple trauma.

METHODS AND ANALYSIS

This systematic review protocol was developed in adherence to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines and has been registered with the International Prospective Register of Systematic Reviews under the registration number: CRD42023481761.^{16 17} The extracted data will be analysed qualitatively, and a meta-analysis will not be conducted. This decision is based on the anticipated difficulty of statistical integration due to differences in research methodologies.

Eligibility criteria

Study types

The selection will encompass both randomised and non-randomised controlled trials to evaluate interventions for nipple trauma during breastfeeding.

Participants

This review will consider studies involving lactating women experiencing nipple trauma.

Interventions and comparators

In our study, moisturising therapy is defined as a consistent and tangible intervention that encompasses the nipple, including devices such as nipple shields, polyethylene film dressings, silver-impregnated medical caps and hydrogel dressings. Additionally, breast shells, which do not make direct contact with the nipple, are classified as a separate intervention, in line with the methodology of our research. It is important to distinguish that interventions involving the topical application of substances like HPA lanolin or coconut oil to the nipple are considered independent intervention methods. The study will evaluate various control groups but will primarily concentrate on non-medical lactation aids that tackle nipple pain and damage during breastfeeding. Nipple trauma is defined with reference to ABM (Academy of Breastfeeding Medicine) Clinical Protocol #26: Persistent Pain with Breastfeeding¹⁸ and includes conditions such as breast pump trauma, eczematous conditions and psoriasis. It encompasses a wide range of damages and pain, from acute (such as from a bite) to subacute (non-healing ulcer, blister or milk bleb) to chronic (inflammatory changes secondary to breast pump use, shallow latch, hypertrophied milk bleb, etc). This definition specifically excludes vasospasm, dermatitis and infections, thereby clearly omitting pharmacological treatments for bacterial or fungal infections from the investigation.^{19 20}

Outcome measures

Primary outcomes assessed will include the healing of nipple trauma and reduction of nipple pain. Secondary outcomes may include rates of exclusive breastfeeding and maternal satisfaction with the treatment.

Search strategy

We will conduct searches across various databases, including PubMed, CINAHL, Cochrane Library, Web of Science, CiNii Research in Japan, Ichushi-Web and databases containing grey literature, such as OpenGrey, OpenDOAR and WorldCat. Due to the sparse number of experimental studies in the existing literature, no date limitations will be applied. Furthermore, we will scrutinise systematic reviews and the reference lists of retrieved articles to unearth additional relevant studies. The preliminary search syntax for PubMed is presented in [table 1](#). For additional databases, please see online supplemental file 1. Grey literature will be explored using basic searches with the terms 'nipple pain' and 'nipple trauma'. Our review will focus on literature available in either English or Japanese, intending to conduct the searches from December 2023 and January 2024. After the search, all identified citations will be imported into EndNote and duplicate entries will be removed.

Regarding this systematic review, data management will be conducted using EndNote software to ensure secure data entry and initial data handling. Subsequently, data extraction will be carried out by developing and applying standardised data extraction forms using Microsoft Excel. All procedures will be independently performed by two reviewers, with a third reviewer serving for additional oversight. In the event of encountering missing, incomplete or unclear data within the articles, queries will be addressed to the respective authors.

Data extraction

Two independent reviewers will extract the data. Should there arise any discrepancies, a third reviewer will serve as the adjudicator. The extracted data will encompass details of demographic population, study methodology, year of publication, sample characteristics (including sample size, maternal age, parity, nipple type, nipple colour, type of trauma and any additional methods applied to the trauma) and outcomes (comprising evaluation of nipple tissue healing, improvement in nipple pain, rates of exclusive breastfeeding, women's satisfaction with the intervention and data on breastfeeding).

Risk of bias assessment

The Joanna Briggs Institute (JBI) Appraisal Checklist Tools²¹ will be employed for the appraisal of the included studies. The JBI Appraisal Checklist for randomised controlled trials, which comprises 13 items, will be used for randomised controlled trials, while the JBI Appraisal Checklist for quasi-experimental studies, containing nine items, will be applied for non-randomised trials.

Strategy for data synthesis

Data will be compiled by two independent researchers using a standardised form, which includes the following population, intervention, comparison, outcome and study design information.

Patient and public involvement

Patients and/or the public have not been involved in formulating the research question, designing the protocol or devising the dissemination plans for this study.

Ethics and dissemination

Ethical approval is not necessitated as this study does not involve human participants. The findings will be disseminated through publication in a peer-reviewed journal.

DISCUSSION

Numerous comparative studies have been conducted to investigate various methods for preventing and treating nipple trauma. These interventions cover a broad spectrum of approaches, including educational interventions,^{22–24} interventions targeting infants, such as tongue-tie division,^{25 26} osteopathic manipulative treatment²⁷ and topical applications. Even when focussing specifically on nipple interventions, there is a wide variety of substances being applied, presenting a significant challenge in fully understanding these methodologies, particularly when considering innovative interventions that are reflective of the cultural and traditional practices prevalent in different countries. Research in this area demonstrates substantial heterogeneity across varied populations, study designs and potential biases within the research settings.¹¹ This systematic review aims to comprehensively assess whether interventions pertain to moisture management, thereby aiding the selection of treatment strategies and contributing towards the development of more robust evidence for improved treatments of nipple trauma.

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ORCID iDs

Maya Nakamura <http://orcid.org/0000-0001-8840-6985>

Yunjie Luo <http://orcid.org/0000-0003-4201-8316>

Yasuhiko Ebina <http://orcid.org/0000-0002-4119-7546>

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