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Research Paper

The Effect of Topical Application of Ostrich Oil on the Severity of Nipple Fissure in Breastfeeding Mothers: A Randomized Controlled Trial Protocol

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ABSTRACT

Aims Nipple fissure is a common problem in the first days after delivery that can lead to early cessation of breastfeeding. This study aimed to determine the effect of topical application of ostrich oil on the severity of nipple fissure in breastfeeding mothers.

Materials & Methods A randomized clinical trial was conducted on 48 breastfeeding women with nipple fissure in the first 6 weeks after delivery. In the intervention group (n = 24), mothers were asked to apply five drops of 100% pure ostrich oil five times a day after breastfeeding, and in the control group (n = 24), five drops of their own milk on the affected nipple and areola, and continued this practice for 7 days. On days 3 and 7 after the start of the intervention, participants were examined in person, and the Storr scale was used to assess the severity of the fissure.

Findings The primary objective of this study is to determine the effect of topical application of ostrich oil on the severity of nipple fissures in breastfeeding mothers. If nipple fissures are improved as the primary outcome, breastfeeding will be better, infant weight gain will increase, and mothers will be less inclined to use powdered milk. These outcomes help researchers accurately assess the effectiveness and safety of the intervention under study.

Conclusion The results of this study can provide evidence to support the effect of topical application of ostrich oil in reducing the severity of nipple fissure in breastfeeding mothers. If this oil shows positive effects and does not have serious side effects, it can be hoped that it can be used as an effective treatment option for breastfeeding mothers who are facing the problem of fissured and sore nipples. These findings can help improve the quality of life of breastfeeding mothers and promote successful and healthy breastfeeding in society.

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Introduction

The World Health Organization recommends breastfeeding as the gold standard for infant nutrition [1-3]. Breastfeeding is the most effective way to reduce infant mortality and has many benefits for maternal health [4]. However, some factors reduce or stop breastfeeding, such as nipple fissure. Nipple fissures are sores on the nipples of breastfeeding mothers, typically occurring in transverse, star, or lower marginal shapes [5, 6]. Its highest prevalence is 3-7 days after delivery [7, 8]. According to reports, 34%-96% of breastfeeding mothers experience nipple fissures, causing ineffective breastfeeding [9]. The causes of nipple fissures include improper attachment of the baby's mouth to the breast, ineffective sucking of the baby due to organic and functional causes, inappropriate positioning of the baby, short frenulum, tiny tongue, use of a breast pump, infection with Candida albicans, use of pacifiers and powdered milk for the baby, and removal of the breast from the baby's mouth before stopping sucking [5, 10]. Rapid and effective treatment of nipple fissures plays a key role in increasing mothers' self-confidence and prolonging their breastfeeding period [10, 11]. According to traditional medicine, ostrich oil is effective for wound healing [12]. The ostrich is the largest and oldest bird in the world, and ostrich oil constitutes 15% of its weight [13]. The predominant fatty acids in ostrich oil and breast milk fat are similar and include oleic, palmitic, stearic, and linoleic acids [14]. This product contains varying amounts of carotenoids, flavones, polyphenols, tocopherols, and phospholipids in the triglyceride portion, which are used for antioxidant effects [15]. This oil has been used in folk medicine as a topical treatment for eczema, psoriasis, dry skin, contact dermatitis, burns, hair loss, bedsores, and muscle pain [13]. The use of ostrich oil in producing infant powdered milk showed no statistically significant difference in the quality characteristics of the powder, compared to those formulated with vegetable oils. Ostrich oil can be introduced as a new source of edible oil [14]. The study titled "The effect of topical application of ostrich oil on healing of *Staphylococcus aureus* and *Pseudomonas aeruginosa* infected wounds" was designed to analyze the accelerating effect of this application on infected wounds in a mouse model. In total, 72 BALB/c mice were divided into four main groups: sham control, mupirocin, and two treatment groups with 2% and 4% (w/w) concentrations of ostrich oil applied topically. The results showed that ostrich oil may be beneficial for treating infected skin wounds [16]. Given the importance of breast milk for the growth and development of infants, necessary measures should be taken to ensure exclusive breastfeeding. However, nipple fissures may result in premature weaning before the minimum recommended period of 6 months of exclusive breastfeeding with breast milk [17, 18]. With this background in mind, the present study aimed to determine the effect of topical application of ostrich oil on the severity of nipple fissures in breastfeeding mothers through a clinical trial.

Research Objectives and Hypotheses

The general aim of this study was to determine the effect of topical application of ostrich oil on the severity of nipple fissures in breastfeeding mothers. Specifically, the mean score of the severity of nipple fissures in breastfeeding mothers was compared between the control and intervention groups before and after the intervention. The research hypothesis stated that the mean score of the severity of nipple fissures in breastfeeding mothers after the intervention would differ between the control and intervention groups.

Trial Design

This article describes the protocol of a randomized, controlled, parallel-group clinical trial (1:1 allocation ratio) registered with the Clinical Trials Center (IRCT: 20240317061315N1) on March 27, 2024. The protocol was designed based on the SPIRIT 2013 checklist, and the study process is summarized in Figure 1.

Materials and Methods

Participants, Interventions, and Outcomes

The statistical population included all breastfeeding mothers with nipple fissures who referred to public and private comprehensive health service centers in Gonabad, Iran, during the first 6 weeks after delivery in 2023. The participants were selected using convenience sampling. The eligibility criteria for participation included a minimum score of 3 on the Storr scale, exclusive breastfeeding, a newborn birth weight between 2500 and 4000 grams, and singleton delivery. In addition, the nipple fissure had to occur within the first six weeks after delivery, and the mother had to express willingness to participate in the study. The non-inclusion criteria encompassed mothers with breast abnormalities, such as inverted or large nipples or a history of breast surgery; mothers with breast diseases or skin allergies, mental or psychological disorders, or a known allergy to ostrich oil based on self-report; and mothers using a breast

pump or nipple shield. Infants with oral candidiasis, congenital oral or maxillofacial anomalies, or a short frenulum, based on clinical observation, were also excluded. Moreover, feeding infants with a bottle, powdered milk, boiled water, or sugar water; the use of other topical wound-healing creams; or the use of medications that suppress lactation, such as cabergoline, bromocriptine, and Dostinex tablets, based on the mother's statement, were considered exclusionary. The exclusion criteria further included women with dysentery or breast infection, failure to continue treatment for seven days, inability to communicate by phone or in person during follow-up examinations, use of other topical wound-healing creams during the study period, and unwillingness to continue participation. This study used 100% pure ostrich oil in the intervention group and breastfeeding in the control group. In the intervention group, each participant was given a bottle containing 25 mL of ostrich oil and instructed to apply five drops to the nipple and areola five times a day after breastfeeding, continuing this regimen for seven days. Mothers were asked to keep the oil on the nipple and areola for one hour. If the infant becomes hungry, they should wash and dry the nipple with lukewarm water and then add a dose of medicine instead [19].

Explanation for the Choice of Comparators

The comparison group was selected based on scientific criteria and research objectives to investigate the real effect of the intervention (ostrich oil) and compare it with the usual conditions. In the intervention group, ostrich oil was investigated as a treatment option due to its anti-inflammatory, moisturizing, and wound-healing properties. This intervention was selected to explore the potential effects of this substance on the improvement of breast fissures in breastfeeding women. In the control group, breastfeeding was chosen as the natural and standard treatment for breast fissures. Breastfeeding contains antimicrobial and healing agents and is widely recommended for breastfeeding mothers as a simple and accessible method. Breastfeeding is readily available to all mothers and does not require external assistance. The anti-inflammatory and antiseptic properties of breastfeeding are known to be a simple and effective method for controlling inflammation. Both groups were required to use ostrich oil or breastfeeding five times a day after breastfeeding to create the same conditions for testing effectiveness. Both groups were carefully instructed on how to store, wash, and monitor for side effects to minimize the possibility of external or confounding factors. Selecting breastfeeding as the control group allowed for a direct comparison of the effectiveness of ostrich oil with an accepted, natural treatment. This design not only assesses the therapeutic effect of the new intervention but also provides credible and reliable evidence of its superiority or non-inferiority compared to conventional methods.

Intervention Description

In the intervention group, each participant was given a bottle containing 25 mL of ostrich oil and was instructed to apply five drops to the nipple and areola five times a day after breastfeeding, continuing this for seven days. Mothers were asked to keep the oil on the nipple and areola for one hour. If the infant became hungry during this time, the mother was asked to wash and dry the nipple with lukewarm water and add a dose of medicine instead. Mothers were instructed to store the bottle at room temperature, out of direct sunlight, in a cool, dark place with the lid closed. They were also advised to initially place a few drops of the oil on their forearm before use, and to use it after 30 minutes if there was no swelling or redness. In the control group, breastfeeding mothers with nipple fissures placed five drops of their milk on the nipple and areola five times a day after breastfeeding.

Criteria for Discontinuing or Modifying Allocated Interventions

In this study, participants who did not agree to continue, failed to comply with the study protocols, or experienced significant side effects would be withdrawn. During the intervention, the research units in both groups were visited in person on days 3 and 7 after the intervention began, and were reviewed for exclusion criteria. Participants were assessed according to the exclusion criteria, and those meeting any of these criteria were excluded from the study. If the nipple fissure worsens or does not improve, the child will be referred to a specialist, and the mother will be excluded from the study.

Strategies to Improve Adherence to Interventions

In-person and virtual educational sessions were held for breastfeeding mothers to discuss the importance and benefits of various interventions, especially the use of ostrich oil. Regular follow-ups with mothers were conducted to review progress and answer their questions.

Relevant Concomitant Care Permitted or Prohibited During the Trial

In the intervention group, the use of any prescribed topical medication except ostrich oil, and in the control group, except breastfeeding on the nipple and areola for the treatment of nipple fissures, or any alternative

or complementary therapies whose effect on the study results is unknown, is prohibited. In addition, any significant changes in breastfeeding practices that may impact the study results must be made in consultation with the research team.

Outcomes

In this study, the primary outcome was improvement in nipple fissures. The primary objective of this study is to determine the effect of topical application of ostrich oil on the severity of nipple fissures in breastfeeding mothers. If nipple fissures are improved as the primary outcome, breastfeeding will be better, infant weight gain will increase, and mothers will be less inclined to use powdered milk. These outcomes help researchers accurately assess the effectiveness and safety of the intervention under study. The schedule of participant enrollment, intervention, and evaluation in the study is presented in Table 1.

Table 1. Study Enrollment, Intervention, and Evaluation Schedule

Study Period	Enrolment	Allocation	Post-allocation	Close-out
Timepoint	-t1	t0	t1	t2
Enrolment				
Eligibility screen	×			
Informed consent	×			
[Other procedures]	×			
Allocation		×		
Interventions:				
[Intervention A]			×	
[Intervention B]			×	
Assessments:				
[Baseline variables]	×			
[Outcome variables]	×		×	×

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Provisions for Post-trial Care

In the event of any complications or problems for participants during or after the study, necessary measures were taken to provide post-study care. If required, participants will have access to appropriate medical and treatment services to ensure full recovery and prevent long-term complications. The research team was also committed to examining the participants' health status after the study's end and providing the necessary counseling.

In the case of any harm resulting from the research intervention, necessary measures were taken to compensate the participants and provide financial or medical support. Participants also receive the required training on self-care and complementary therapies (if required) to help maintain and enhance their health. An emergency contact number was provided so that participants could contact the research team directly in case of an emergency. These measures were designed to respect the rights and safety of participants and are part of the ethical obligations of research.

Participant Timeline

After the proposal was approved, the code of ethics was obtained, the study was registered with the Iranian Clinical Trial Registration Center, a written introduction to the Deputy Health Office and permission to enter the comprehensive health service centers of Gonabad were received, the necessary coordination with the centers was made, and sampling began. After explaining the study's objectives and obtaining informed consent to participate, the research unit selection form was provided to the mothers. Those who met the inclusion criteria were then included in the study. The study subjects completed the demographic characteristics form, and the presence of unilateral or bilateral nipple fissure was checked. The researcher then completed the fissure severity measurement scale. The subjects were then divided into two groups based on random allocation with permuted blocks of four, and interventions in each group were performed according to predetermined instructions. The intervention was conducted for 7 days in both groups. On days 3 and 7 of the intervention, the severity of the nipple fissure was examined and measured using the Storr scale. On days 3 and 7, 100% pure ostrich oil was used in the intervention group and control group, respectively. Each research unit was given a bottle containing 25 mL of ostrich oil and asked to place five drops on the nipple and areola five times a day after breastfeeding, continuing this for seven days. In the control group, breastfeeding mothers placed five drops of their milk on the nipple and areola 5 times a day after breastfeeding. Figure 1 illustrates the study's flowchart.

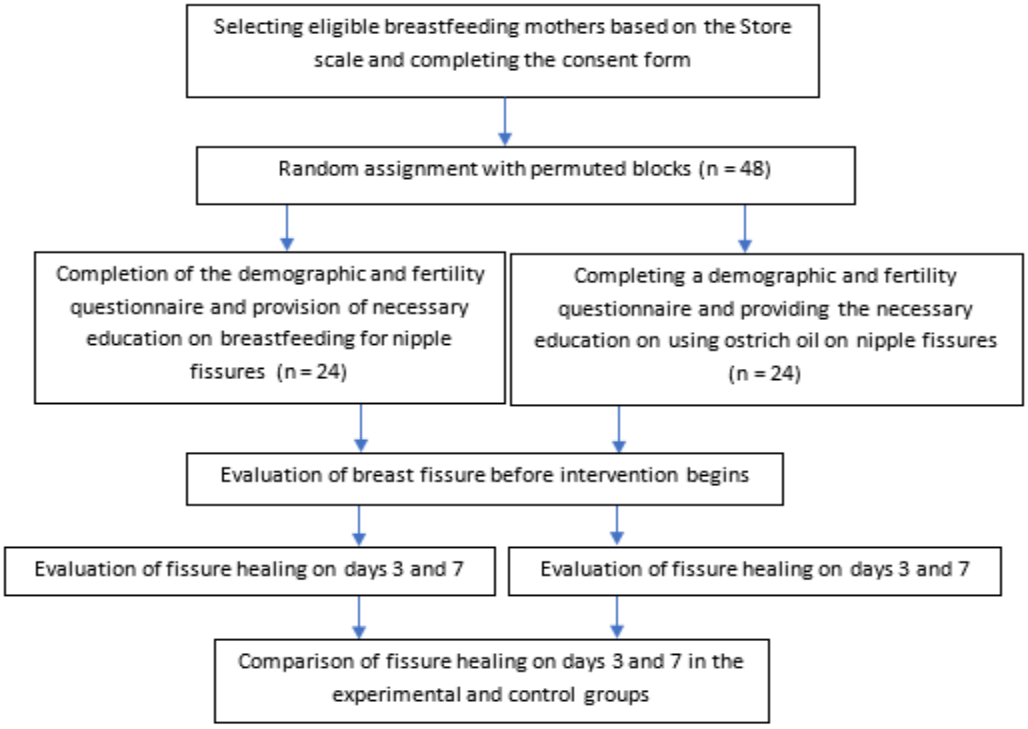

Figure 1: Study Flow Chart

Sample Size

The sample size was determined using G* Power 3.1.9.2 software, based on the formula for comparing the means of two independent groups. Considering a confidence level of 95%, power of 90%, mean values of 2.72, and standard deviation of 0.45 based on a similar study [19] and an expectation of at least a 0.5-unit reduction in breast engorgement score, 19 subjects were determined for each group, which was increased to 24 subjects in each group due to a 25% probability of loss.

Recruitment

In this study, precise inclusion and exclusion criteria were established to select participants, ensuring that suitable individuals were included in the study. After explaining the research objectives to breastfeeding mothers with nipple fissures during the first six weeks after delivery who are referred to comprehensive health service centers in Gonabad, an informed consent form (Appendix 3) was provided to the mothers for their participation in the study. If they met the inclusion criteria, they were included in the study, and mothers were visited in person on days 3 and 7 after the intervention.

Methods: Assignment of Interventions Allocation: Sequence Generation, Concealment Mechanism, and Implementation

Sampling was non-random (convenience), and permuted blocks of 4 were used to assign samples to the two intervention and control groups randomly. Computer-generated random numbers were used to generate the allocation sequences. A statistical consultant prepared this list and randomly selected the blocks. Blocks of four with equal numbers of both intervention and control groups in each block, and registration of participants and their allocation to interventions were performed by the research team to prevent bias.

Assignment of Interventions: Blinding Who Was Blinded

In this study, blinding was strictly adhered to by the data analyst to prevent bias in the analysis of results. After the interventions were allocated, the data analysts were unaware of the type of intervention assigned to each participant. For this purpose, the study groups were identified as codes A and B. This coding allowed analysts to analyze the data without knowing the intervention type and to evaluate the results objectively.

Methods: Data Collection, Management, and Analysis Plans for Assessment and Collection of Outcomes

In this study, the following tools were used to collect information:

1. Research unit selection form: This included inclusion criteria at the beginning of the study and exclusion criteria during the intervention. This form

was prepared according to the research objectives, the latest sources, relevant articles, and consultations with supervisors and consultants.

2. Demographic and fertility characteristics data checklist: This included two parts: a) Demographic information, b) Information related to fertility.

a) Demographic characteristics: This included variables, such as maternal age in years, maternal occupation, maternal weight in kilograms, and maternal education level. (Appendix 1)

B) Characteristics related to fertility: This included variables, such as number of pregnancies, time of onset of postpartum fissure, type of delivery, complications of delivery, number of nipples with fissure, completion of prenatal breastfeeding education courses, previous breastfeeding problems, time of initiation of first breastfeeding after delivery, number of breastfeeding times during the day and night, breastfeeding methods (cradle position, cross-cradle position, side lying, football or clutch hold, supine), birth weight of the infant, age of the infant, and time of fissure formation. The validity of the research unit selection form and demographic and obstetric information checklist was determined based on content validity. Initially, these forms were developed using reliable sources and new articles under the supervision of supervisors and consultants. Then they were made available to university faculty members, and amendments were made according to the opinions of these professors.

3. Storr Scale: This scale was used to assess the severity of breast fissures.

This scale had five items, and scores range from 0 to 4 [20]. The Storr Scale was scored as follows [21]:

Nipple fissure assessment	Score
Nipple without pain and normal color	0
Slightly red nipple and painful only at the beginning of breastfeeding	1
Red nipple and painful only at the beginning of breastfeeding and between breastfeeding	2
Nipple crack with pain at the beginning of breastfeeding and between breastfeeding	3
Nipple sore or cracked with or without bleeding and pain at the beginning of breastfeeding, during breastfeeding, and between breastfeeding	4

4. Informed Consent Form: It included information about the project introduction, benefits, potential risks, work methodology, information confidentiality, answering questions, right to withdraw, and exiting the study.

Ostrich Oil Consumption Registration Form by Breastfeeding Mothers

This form was completed to record breastfeeding mothers' topical use of ostrich oil.

6. Side Effects Registration Form: This form was prepared to investigate the potential side effects of applying ostrich oil topically to the nipple.

Plans to Promote Participant Retention and Complete Follow-up

To ensure participant retention and completion of follow-up, we planned to maintain ongoing communication with the participants. This communication included regular text messages or phone calls to remind and encourage continued participation. These communications also provided updates on the study's progress and emphasized the importance of the involvement. If participants have any questions or concerns, the research team will be available to provide guidance and support. If participants withdraw from the study, information about their reasons for withdrawal will be collected to identify factors affecting withdrawal and to consider in future studies.

Data Management

To ensure the quality and security of the data, it was collected electronically and entered into SPSS software. All data were appropriately coded to facilitate data analysis. Data security was of utmost importance; therefore, access to data was restricted to authorized members of the research team, and all members were required to adhere to ethical principles and maintain participant privacy. Data were stored electronically in standard formats, and regular backups were made so that data could be retrieved in the event of any problem.

Statistical Methods

Statistical Methods for Primary and Secondary Outcomes

After data collection and coding, data analysis was performed using SPSS software (version 21). Mean and standard deviation were used to describe quantitative variables, and numbers and percentages were used for qualitative variables. The normality of quantitative variables was checked using the Kolmogorov-Smirnov test. To compare quantitative variables in two groups, an independent *t-test* was used if normal or a Mann-Whitney test if non-normal, and to compare qualitative variables, a chi-square test or an exact test was used. Generalized estimating equations were used to compare the severity of congestion in two groups. The significance level was set at 5%.

Methods: Monitoring

Data Monitoring

The intervention stages were supervised by a supervisor introduced by the University Ethics Committee.

Harms

During the intervention, research units were reviewed to determine if they met the exclusion criteria. If any of these criteria are met, they will be excluded from the study. If there is no improvement or the severity of the fissure worsens, they will be referred to a specialist physician.

Harms

Ethics Approval and Consent to Participate

This study was registered with the Research Ethics Committee of Gonabad University of Medical Sciences with the approval number IR.GMU.REC.1402.012, and in the Iranian Clinical Trial Registration Center (20240317061315N1: (IRCT) dated 03/27/2024. Informed and written consent were obtained from the participants. Participants were assured that their details and information remained confidential, and the results were announced in general. They were also assured that they could withdraw from the study at any time and that they would not experience any physical or psychological harm during the study. Questions from the research units were answered at the beginning and throughout the study, and all training was provided free of charge. The researcher's contact number was provided to all participants so that they could contact him in case of any questions or concerns. The rights of the authors in all publications resulting from this research were respected. The results of the research were provided to the couples participating in the study if they requested it and wished to do so. Educational content was also sent to couples in the control group after the study.

Plans for Communicating Important Protocol Amendments to Relevant Parties (e.g., Trial Participants, Ethical Committees)

Any crucial changes to the study protocol, such as modifications to eligibility criteria or outcomes, were communicated to all relevant parties. Study participants were informed of these changes through direct communication methods, such as phone calls, text messages, or face-to-face meetings. A full explanation of the changes and their impact on participants was provided to ensure that their informed consent is maintained. Also, any amendments to the protocol were submitted to the ethics committee for review and approval. A formal notification was provided, including details of the changes and necessary justifications. All researchers involved in the study were promptly informed of these changes through team meetings, emails, or internal memos, ensuring that all team members were aligned and could adjust their roles and responsibilities accordingly. If necessary, essential changes to the protocol were updated in the Iranian Clinical Trial Registry to maintain transparency and provide accurate information to the public and other stakeholders.

Who Obtained Informed Consent?

In this study, the research team obtained informed consent from all participants. First, the objectives of the study, study method, and possible benefits and risks were explained to the mothers. Their questions were answered, and the research unit selection form was provided to them. If they meet the conditions and agree to participate in the study, a written informed consent form will be provided.

Confidentiality

In this study, personal information from participants was collected only at the initial stages, and access to this information was limited to authorized members of the research team. No identifying information was included in published results. All research team members were required to adhere to the principles of confidentiality and research ethics. The information collected was used solely for research purposes and in accordance with relevant laws and regulations. After the study was completed, the data were stored in a secure environment, and all identifying information was removed before sharing with other researchers. In addition, participants had the right to withdraw from the study at any stage, and if they chose to do so, their information was deleted entirely.

Declaration of Interest

The authors declared no conflict of interest.

Availability of Data and Materials

Data supporting the findings of this study are available from the corresponding author upon request.

Ancillary and Post-trial Care

After the study was completed, participants had the right to be informed of the study's results; therefore, the results were presented to them concisely and understandably so that they could benefit from the information obtained. At the end of the study, if mothers in the control group wish, they will also be provided with ostrich oil. Additionally, mothers will be referred to a specialist if the fissure does not improve or if its severity worsens. (Possible Complications Form, Appendix 2).

Dissemination Plans

After completing the study and analyzing the data,

the results were presented to participants, health workers, and other relevant groups to inform them of the study's findings. The results were then officially published as a scientific article in reputable health-related scientific journals.

Discussion

Human milk provides infants with numerous bioactive factors, including immunomodulatory components, antimicrobials, and prebiotics, which modulate the infant microbiome and immune maturation [22]. As a result, breastfeeding can affect infant health from infancy to adolescence and adulthood. Given that breastfeeding is an ideal method for infant growth and development, and provides all the nutrients they need, the health of the infant, the mother, and nipple fissure, a common problem in the first days of delivery, can cause pain and discomfort and lead to early cessation of breastfeeding [6, 23, 24]. To date, solutions or sprays, topical ointments, exposing the nipples to light and air, teaching the mother proper breastfeeding techniques, placing a few drops of breast milk on the nipples, hydrogel, dexpanthenol, lanolin, aloe vera, hot water compress, peppermint extract, collagenase ointment, and aqueous-alcoholic extract of curcumin extract have been used to treat nipple pain and prevent nipple fissures [25, 26].

It is beneficial to leave some milk on the nipple and let it dry independently because breastfeeding has antiseptic and emollient properties [18]. This study aims to compare the effects of ostrich oil and breastfeeding on the healing of nipple fissures, suggesting an effective treatment to reduce healing time, alleviate pain, and prevent postpartum breast abscesses. It also aims to take practical steps towards promoting continued breastfeeding and increasing exclusive breastfeeding. Studies conducted using ostrich oil on skin wounds in animal models have shown that this oil extract can have sound effects on wound healing and pain reduction due to its antioxidant, anti-inflammatory, and antimicrobial compounds. Eshghizadeh et al. (2016) observed a significant improvement in the severity of breast fissures from the first to the seventh day of intervention in the breastfeeding group [7].

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Appendices

Demographic and Fertility Checklist (Appendix 1)

A: Personal Information
1-How old are you?.....years
2-How many kilograms do you weigh?.....kilograms
3-What is your level of education? 1 - Elementary 2- Diploma 3- Bachelor's degree 4- Master's degree and above 5-illitrate
4-What is your occupation? 1 - Housewife 2- Employee 3- Worker 4 - Home occupation
B: Information about breastfeeding and the newborn
1-How many grams did the newborn weigh at birth?..... grams
2-What was your delivery method? 1- Natural 2- Cesarean
3-How many times have you been pregnant?..... times
4-How many days is the baby old?..... days
5-When was the first breastfeeding?.....hours after delivery
6-How many times a day do you breastfeed your baby?.....times
7-How many days after delivery did the fissure appear?.....days
8-How many nipples are affected by fissure? 1-one 2-two
9-Have you attended breastfeeding education courses before delivery? 1-Yes 2-No
10-Have you had problems with breastfeeding before? 1-yes 2-no
11-What is the breastfeeding position? 1-cradle position 2-cross cradle position 3-lying on the side 4-supine

Possible Research Complications Form (Appendix 2)

Type of complication	It occurs the day after the intervention.
Skin irritation and inflammation	
Skin rash	
Other cases	

Informed Consent: (Appendix 3)

Consent to participate in the research project: The effect of topical application of ostrich oil on the severity of nipple fissure in breastfeeding mothers, Gonabad City, 2024

Dear Madam
You are invited to participate in this study. Information about this research is provided in this form, and you are free to participate or not to participate in this research.
You are not obligated to make an immediate decision, and you can ask the research team any questions you may have and consult with anyone you wish to make this decision. Before signing this consent form, please ensure that you understand all the information in this form and that all your questions have been answered.
Research Administrator

I understand that this study's objectives include:
The effect of topical application of ostrich oil on the severity of nipple fissure in breastfeeding mothers, Gonabad City, 2024

1 . I understand that my participation in this study is completely voluntary and that I am not forced to participate. I was assured that if I did not agree to participate, I would not be deprived of routine diagnostic and therapeutic care, and my therapeutic relationship with the treatment center and my treating physician would not be affected.

2. I understand that even after agreeing to participate in the study, I can withdraw from it at any time, after informing the researcher, and my withdrawal will not result in my being deprived of receiving routine medical services.

3 . I was assured that if the study's implementation changes or new information is obtained during the study that may change my decision to continue participating, I will be notified, the University Ethics Committee will be notified, and I will be required to complete the informed consent form.

4 . The potential benefits of my participation in this study are as follows:
Participation in this study will improve my nipple fissure. If the effect of ostrich oil is better than breastfeeding, my nipple fissure will heal faster. After the study is completed, the researcher will provide me with the results upon my request.

5 . The possible harms and complications of participating in this study are as follows: possibility of allergy to ostrich oil, redness, or itching.

6. I was assured that if this study is terminated or suspended for any reason outside the scheduled time, I will be informed in a timely manner, appropriate treatment will continue for me, and I will not be abandoned.

7. If I do not wish to participate in the study, I will be offered the usual treatment method, the benefits and complications of which are as follows:
If I do not wish to participate, the questionnaire will not be completed.

8. I understand that the people involved in this study will keep all information about me confidential and are only allowed to publish the general and group results without mentioning my name, or details.

9 . I understand that the Research Ethics Committee may have access to my information to monitor compliance with my rights.

10. I understand that I will not be responsible for any costs associated with the research interventions described below.

11. Ms. Zohreh Pourgheisar was introduced to me as the person responsible for this research. I was instructed to contact her whenever I had any problems or questions regarding participation in the study and to seek guidance.

Her address, landline, and mobile phone numbers were provided to me as follows:

•Researcher's address: Gonabad University of Medical Sciences, Faculty of Medicine
•Researcher's mobile phone: 09153000383

12. I understand that if any physical or mental problems occur during or after the research due to my participation in this research, the treatment of complications, their costs, and related compensation will be the responsibility of the researcher.

13 . I understand that if I have any problems or objections to the participants or the research process, I can raise my problem verbally or in writing with the Research Ethics Committee of Gonabad University of Medical Sciences.

14 . This information and informed consent form was prepared in two copies. After signing, one copy will be given to me, and the other copy will be given to the researcher.

I have read and understood the matters mentioned above, and based on that, I declare my informed consent to participate in this study.

Participant's signature

I, Zohreh Pourgheisar, consider myself obligated to fulfill the obligations related to the researcher in the above provisions and strive to ensure the rights and safety of the participants in this research.

Seal and signature of the researcher