

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of foot reflexology on the breast engorgement lactating mothers

Protocol summary

Study aim

The effect of foot reflexology on breast engorgement in lactating mothers

Design

A randomized clinical trial using two-way blocking method with a control group, parallel groups and a sample size of 80 lactating mothers

Settings and conduct

The study investigated 80 lactating mothers in the first 3-5 days after delivery referring to Mashhad's number one health center for breast engorgement. With observing moral points, obtaining informed consent, explanation of the goals, having the entry and exit conditions, then if the score for breast engorgement was greater than or equal to 2, the sample was selected as the sample. For the intervention group, in addition to routine care, reflexology of the foot performed daily by a mother for a period of 20 minutes. The control group received a routine care (lactation technique training, repeated feeding, warm compress).

Participants/Inclusion and exclusion criteria

Inclusion criteria : Healthy in terms of medical disease or obstetric, Non-use of herbal topical drugs or chemicals, No mastitis, breast abscess and nipple scars, Mothers with body temperature below 38 ° C, Breast engorgement in the first 5 days after delivery, Obtaining a minimum score of 2 out of 19 from the degree of engorgement checklist, Non-use of Antibiotic, Breastfeeding, Gestational age 37-42 weeks, Age of a neonate 3-5 days, singleton birth Exit criteria: The use or need of any anti-inflammatory drug, or the occurrence of mastitis or breast abscess during the study, non-lactation

Intervention groups

The intervention group, foot reflexology and routine care control group

Main outcome variables

Consequences: The degree of breast engorgement severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190608043838N1**

Registration date: **2019-06-19, 1398/03/29**

Registration timing: **retrospective**

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

Registration date

2019-06-19, 1398/03/29

Registrant information

Name

Fatemeh Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-01-20, 1397/10/30

Trial completion date

2019-01-20, 1397/10/30

Scientific title

The effect of foot reflexology on the breast engorgement lactating mothers Public title The effect of complementary medicine on breast engorgement Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: Iranian, Mashhad citizens Reading and writing skills Informed consent of willingness to participate in the study Contact number Healthy in terms of medical disease or obstetric Non-use of herbal topical drugs or chemicals No history of breast surgery No mastitis, breast abscess and nipple scars Mothers with body temperature below 38 ° C Breast engorgement in the first 5 days after delivery Obtaining a minimum score of 2 out of 19 from the degree of engorgement check list Non-use of Antibiotics Breastfeeding and willing to lactation Gestational age of 42 to 37 weeks Age of a child 3-5 days Singleton birth Exclusion criteria: Increase in temperature up to more than 38 ° C The use or need of any anti-inflammatory drug during the intervention Reluctance to continue cooperation in the study The occurrence of mastitis or breast abscess during the study Non-lactation Age No age limit Gender Female Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 80 Actual sample size reached: 80 Randomization (investigator's opinion) Randomized Randomization description Distribution of subjects into two groups (intervention, control) was done by random allocation using two-way blocking method via software. Since no contact between participants in the two groups was a principle, so the individual randomization was done in a special way based on the week days. Considering that individuals should have consulted two days after the first visit to assess the severity of engorgement, new participants who were going to included in the study should joined on Saturday or Sunday (the first group on Saturday and the second group on Sunday), thus choosing one of the two intervention or control groups as the first or second group was randomly (using a coin). Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel	Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee The Ethics Committee of Mashhad University of Medical Sciences Street address No. 41 , Daneshjo street 34, City mashhad Province Razavi Khorasan Postal code 9188955395 Approval date 2018-06-19, 1397/03/29 Ethics committee reference number IR.MUMS.NURSE.REC.1397.014 Health conditions studied 1 Description of health condition studied Breast engorgement in the lactating mothers ICD-10 code N64.89 ICD-10 code description Other specified disorders of breast Primary outcomes 1 Description Obtaining minimum score 2 out of 19 from the breast engorgement check list Timepoint The first day before and after intervention, the third day after intervention Method of measurement Standard breast engorgement score check list Secondary outcomes 1 Description Breast pain severity Timepoint The first day before and after intervention, the third day after intervention Method of measurement
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Pain visual matching scale

2

Description

Number of previous pregnancies

Timepoint

Study in the end

Method of measurement

Statistical tests

3

Description

Type of delivery

Timepoint

Study in the end

Method of measurement

Statistical tests

4

Description

History of breastfeeding

Timepoint

Study in the end

Method of measurement

Statistical tests

Intervention groups

1

Description

Intervention group: Foot reflexology was performed for 20 minutes, 10 minutes on each foot, in three zones of the solar network (3 minutes), breast(3 minutes), lymphatic system(3 minutes). One minute was allocated for general massage, once a day for three consecutive days by mothers.

Category

Treatment - Other

2

Description

Control group: Routine care(correct lactation training, frequent lactation, hot compress)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad's health center number one

Full name of responsible person

Fatemeh Mousavi

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2

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Name of recruitment center

Hojjat health care center

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3

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Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Mashhad University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 Public
Domestic or foreign origin
 Domestic
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 Academic

Person responsible for general inquiries

Contact
Name of organization / entity
 Mashhad University of Medical Sciences
Full name of responsible person
 Fatemeh Mousavi
Position
 Master of midwifery student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
 Yes - There is a plan to make this available
Statistical Analysis Plan
 Yes - There is a plan to make this available
Informed Consent Form
 Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
 Yes - There is a plan to make this available
Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the required data provided in the thesis

When the data will become available and for how long

Right after publishing the thesis and the article

To whom data/document is available

Students and researchers

Under which criteria data/document could be used

In case of attaining faculty library permission

From where data/document is obtainable

Faculty of nurse and midwifery, Ibne Sina st, Mashhad,
Iran Tel: 00985138591511

What processes are involved for a request to access data/document

It's referred to published article and faculty library

Comments