

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of hand reflexology and foot reflexology on mastalgia among female college student

Protocol summary

Study aim

Comparison of the effect of hand reflexology and foot reflexology on periodic breast pain

Design

The study was conducted on the 90 female students suffering from cyclic breast pain. The participants were selected using the purpose sampling technique and divided into three groups: hand reflexology, foot reflexology and control. Prior to the study, the participants passed a reflexology massage training course and received educational pamphlets. An 8-minute session of reflexology was performed by the hand and foot reflexology groups in the last 14 days of two menstrual cycles. The severity of the periodic pain of the breast was measured by the pain visual scale and the duration of the pain was recorded in the daily pain table. Finally. The duration and severity of mastalgia changes were compared.

Settings and conduct

The place of sampling was Girls' dormitories

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 15-45 years; BMI between 19.6_2; The length of menstrual cycle be regular and ranges between 21-35 days; breast pain during the last 14 days of the menstrual cycle; The average score of pain severity on the visual analogue scale be equal to 30-69. Non-inclusion criteria: Eating rich-fat diet or xanthine; being pregnant or intending to become pregnant during the study; Breastfeeding; Using hormonal medications since the last three months; Presence of abnormality in breast examination.

Intervention groups

The control group recorded the duration and severity of cyclic breast pain in the daily pain table and pain visual scale. Hand reflexology group performed an 8 -minute session of reflexology on the breast, upper lymphatic system and solar plexus zones in hands and filled daily forms. Foot reflexology group also performed reflexive massage on the mentioned zones in feet and filled forms.

Main outcome variables

Severity and duration of mastalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170508033868N2**

Registration date: **2018-05-01, 1397/02/11**

Registration timing: **retrospective**

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

Registration date

2018-05-01, 1397/02/11

Registrant information

Name

Hamideh Safari

Name of organization / entity

Mashhad University of Medical Sciences Nursing and Midwifery Faculty

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

safarih941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of hand reflexology and foot reflexology on mastalgia among female college student

Public title
Comparison of the effect of hand reflexology and foot reflexology on periodic breast pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Filling out the written consent to participate in the research. Being a resident of the female' dormitory of Mashhad University of Medical Sciences. Age range of 15 -45 years. BMI range of 19.6 - 29. Having a regular menstruation cycle ranging from 21 to 35 days. Complaining of breast pain that occurred during the last 14 days of the menstrual cycle. Obtaining a minimum pain intensity score of 30-69 using the visual analogue scale.

Exclusion criteria:

Being a professional athlete: Eating rich-fat diet or diet containing xanthine. Pregnant or intend to become pregnant during the study. Breastfeeding. Experience of bad events in the past three months. Using hormonal medications or contraceptive pills since the last three months. Using the medicine to relieve pain during the last two months. Using a specific method to relieve breast pain. History of breast cancer in herself or her first-degree relatives. History of suspected breast mass in examination, mammography, or ultrasound. History of surgery on the breast or injection of gel or fat Having wound or lesion in the hands or feet. Having specific illness. Presence of physical disabilities. Presence of abnormality in breast examination.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the five dormitories of Mashhad University of Medical Sciences, three dormitories were selected randomly (with a draw) for the control group, hand reflexology group and foot reflexology group.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used
Assignment
Parallel
Other design features
Randomized and three groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Quraishi Building, Daneshgah street, Doctora Intersection, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2017-05-24, 1396/03/03

Ethics committee reference number

IR.MUMS.REC.1396.63

Health conditions studied

1

Description of health condition studied

mastalgia

ICD-10 code

N64.4

ICD-10 code description

Mastodynia

Primary outcomes

1

Description

Duration of pain

Timepoint

Two periods before the intervention and two periods during intervention(after one and two intervention cycles)

Method of measurement

Daily pain registry table

2

Description

Intensity of pain

Timepoint

Two periods before the intervention and two periods

during intervention(after one and two intervention cycles)

Method of measurement

Pain visual Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Without intervention, just in the last 14 days of the menstrual cycle, the duration of the period are recorded in the Daily pain registry table and the severity of periodic breast pain are assessed using pain visual scale.

Category

Diagnosis

2

Description

Intervention group 1: Hand reflexology, Doing daily 8 minutes of reflexology massage zones including Breast, upper lymphatic and solar plexus, on hand(With the intensity that felt numb in the place) in the last 14 days of the menstrual cycle and filling daily forms

Category

Treatment - Other

3

Description

Intervention group 2: foot reflexology, Doing daily 8 minutes of reflexology massage zones including Breast, upper lymphatic and solar plexus, on foot(With the intensity that felt numb in the place) in the last 14 days of the menstrual cycle and filling daily forms.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls Student Dormitories of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Naderzadeh

Street address

Mashhad University of Medical Sciences, Bahonar Blvd, Vakil Abad Blvd.

City

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Postal code

00

Email

safarih941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Quraishi Building, Daneshgah street, Doctora Intersection, Mashhad

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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

Vice chancellor for research 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

Hamideh Safari

Position

Master student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Faculty of Nursing and Midwifery, Doctora
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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahin Tafazoli

Position

MSc in Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Hamideh Safari

Position

Master student Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Web page address**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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available