Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Jacopsen's relaxed body and foot reflexology on breastfeeding adequacy and breast milk volume in premature infants

Protocol summary

Study aim

1- Determining and comparing the effect of Jacopsen relaxation and foot reflexology on breastfeeding adequacy of preterm infants in the two intervention groups 2- Determining the effect of Jacopsen relaxation and foot reflexology on breast milk volume of preterm infants in two intervention groups

Design

The randomized clinical trial with parallel control group.

Settings and conduct

Jacopsen's reflexology and relaxation massage for the intervention group will be performed for nine days in the maternity ward of Ghaem Hospital. The adequacy of breastfeeding will be measured using a questionnaire. They will complete the next day. The milk volume will be measured by the researcher on the first, third and ninth day in two groups using an electric milking machine.

Participants/Inclusion and exclusion criteria

Inclusion criteria in summary include: mother age is a maximum of 20 and a maximum of 35. The mother has no history of breast surgery. Be able to understand writings and verbal instructions, express anxiety verbally. The baby should be between 36-34 weeks old. The baby should be hospitalized in the ward. The baby should not have any other problem. Continue to participate in the study. Occurrence of the disease in the mother during the study. Taking drugs that increase breast milk such as metoclopramide.Neonatal intubation need, vital signs disorder, bleeding, IVH grade 4, long-term NPO of the infant during the study. Maternal discharge earlier than the end of the intervention

Intervention groups

The first group of mothers who experience foot reflexology. The second group of mothers experience Jacobsen relaxation.

Main outcome variables

Sufficient lactation; volume of milk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191207045635N1**
Registration date: **2021-02-02, 1399/11/14**
Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**
Update count: **0**

Registration date

2021-02-02, 1399/11/14

Registrant information

Name

elham khanmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Jacopsen's relaxed body and foot reflexology on breastfeeding adequacy and breast milk volume in premature infants

Public title

Comparison of the effect of Jacopsen's relaxed body and foot reflexology on breastfeeding adequacy and breast milk volume in premature infants

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the mother is between at least 20 and at most 35 years old Be literate, be able to understand writing and verbal instructions, express verbal anxiety. The mother tends to breastfeed The mother has no history of serious or chronic illness, such as cardiovascular disease or mental illness (postpartum depression, schizophrenia, according to the mother), according to the mother. The mother is not addicted to smoking and drugs, especially cocaine and derivatives, as the mother says. The mother does not take drugs that are contraindicated during breastfeeding, such as doxepin tricyclic antidepressants, iodine compounds, gold salts, salicylates, and anticonvulsants during the intervention. The mother has no history of breast surgery and no history of injury or wound at the site of reflexology and no breast problems (fissures, congestion, mastitis and breast abscess). The mother should not take lactation-enhancing drugs, including metoclopramide.

Exclusion criteria:

The mother's unwillingness to continue participating in the research Incidence of disease in the mother during the study. Taking drugs that increase breast milk, such as metoclopramide. Neonatal intubation need, vital signs disorder, bleeding, IVH grade 4, long-term NPO of the infant during the study

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

They will be invited to the study by available sampling and will be randomly divided into two groups of foot reflexology intervention and Jacopsen relaxation without replacement. A simple random selection of one of the groups and sampling will begin.

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

Ethics Committee of Mashhad Collge of Nursing and Midwifery

Street address

Faculty of Nursing and Midwifery, Ibn Sina St., Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.035

Health conditions studied

1

Description of health condition studied

Fetus and newborn affected by other maternal noxious influences.

ICD-10 code

P04.8

ICD-10 code description

Newborn (suspected to be) affected by other maternal conditions noxious substances

Primary outcomes

1

Description

Breastfeeding adequacy score in the breastfeeding questionnaire

Timepoint

Assess the adequacy of breastfeeding before the intervention and twenty-one days after the intervention

Method of measurement

Breastfeeding adequacy questionnaire

Secondary outcomes

1

Description

Volume of milk using a graduated scale one hour after the end of breastfeeding and two hours after the

intervention

Timepoint

The volume of milk in the first days (once), third and ninth of the intervention will be measured one hour after the end of breastfeeding and two hours after the intervention by Philips electric milking machine using a calibrated scale by the researcher in two groups.

Method of measurement

Breast milk will be milked using a Philips electric breast pump and milk volume will be measured using a calibrated gauge.

Intervention groups

1

Description

The first intervention group of foot reflexology: which includes the preparation and warm-up steps and stimulation and massage techniques that will be performed by the researcher once a day for nine days in the rest room of mothers in the nicu ward of Ghaem Hospital. The entire floor and back surface. The foot is massaged for one minute, then the reflex areas of the breast and the solar plexus are pressed and rubbed for 5 minutes for each foot (the intensity of the pressure should be such that it feels numb in position). Mothers are taught how to perform reflexology by a researcher.Milk volume will be measured in the first days (once), third and ninth of the intervention. The volume of the milk will be measured one hour after the end of breastfeeding and two hours after the intervention by the Philips electric milking machine using a graduated scale by the researcher in two groups. The adequacy of breastfeeding in the two groups of mothers on the first day and twenty-one days later at the time of the mother's visit to examine the baby will be assessed by a questionnaire.

Category

Other

2

Description

The second intervention group will experience Jacobs relaxation in nine days in the rest room of mothers in the neonatal ward of Ghaem Hospital by the researcher. In the Jacobsen relaxation group, the mother was first taught the practical technique. Jacobson was practically performed for 35 to 45 minutes by the researcher for the mother. It will be in the form of contracting separate muscles for 5 seconds and then relaxing the muscles for 10 seconds. These movements start first from the muscles of the head, face and neck regularly and in The middle and lower extremities of the body include the contraction of the muscles of the lower back, serine, thighs, legs, and toes.Milk volume will be measured in the first days (once), third and ninth of the intervention. The volume of the milk will be measured one hour after the end of breastfeeding and two hours after the intervention by the Philips electric milking machine using a graduated scale by the researcher in two groups. The adequacy of breastfeeding in the two groups of mothers on the first day and twenty-one days later at the time of the mother's visit to examine the baby will be assessed by a questionnaire.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Elham Khan Mohammadi

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At the beginning of Ahmadabad Street, Dr. Ali Shariati Square, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad School of Nursing and Midwifery

Full name of responsible person

Mohsen Taqfadi

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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 School of Nursing and Midwifery

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
Tahereh Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
After reading the information about the main outcome.

When the data will become available and for how long
10 months after printing

To whom data/document is available

All researchers can apply for it.

Under which criteria data/document could be used

Data and results for all researchers and for research purposes The context of diabetes will be available.

From where data/document is obtainable

SadeghiT@mums.ac.ir

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

The data will be available to the applicant within one month after reviewing and confirming the application Will be located.

Comments