Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of acupressure, OKETANI massage and lactation training on the breastfeeding self-efficacy, quality of breastfeeding, breast milk sufficiency and exclusive breast feeding in nulliparous women

Protocol summary

Study aim
Comparison of the effect of acupressure, OKETANI massage and lactation training on the breastfeeding self-efficacy, quality of breastfeeding, breast milk sufficiency and exclusive breast feeding in nulliparous women

Design
A concealed, randomized, double blinded, parallel group trial with a parallel group design of 120 patients, enrolled between 2021-2022

Settings and conduct
This study is a double-blind clinical trial (researcher and statistical analyst) and has three intervention groups (training group, acupressure group and OKETANI massage group) and a control group that will receive routine care. Therefore, the design is parallel. The statistical population includes all women who refer to Bahar Hospital in Shahroud for delivery. Sampling by method will be available and the samples will be placed in the intervention and control groups using 8-block construction. In the pre-intervention stage, the questionnaire will be completed by someone other than the main intervener. If methodology, the group of people will also be hidden from them.

Participants/Inclusion and exclusion criteria
Age 18 to 35 years. Primipara. Ability to speak Persian and be literate Not having a high-risk pregnancy. Exclusive breastfeeding intention. Giving birth to a full-term and healthy baby who is not prohibited from breastfeeding (such as cleft palate, lips and prematurity).

Intervention groups
The first group of intervention is the group receiving acupressure. The points used in this group are three points GB21,point CV17 and point CO18. The second group of intervention, the group receiving OKETANI massage for 30 minutes once a day for 14 days. The third group is the breastfeeding counseling and training group. and the control group receives only routine postpartum care.

Main outcome variables
Adequacy of breast milk; Breastfeeding self-efficacy: Continuity of exclusive breastfeeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170430033718N5**
Registration date: **2021-02-01, 1399/11/13**
Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**
Update count: **0**

Registration date
2021-02-01, 1399/11/13

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 936 795 8503

Email address
karimifr941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-15, 1399/12/25

Expected recruitment end date
2022-03-16, 1400/12/25

Actual recruitment start date
2021-03-15, 1399/12/25

Actual recruitment end date
2022-03-16, 1400/12/25
Trial completion date
2022-03-16, 1400/12/25

Scientific title
Comparison of the effect of acupressure, OKETANI massage and lactation training on the breastfeeding self-efficacy, quality of breastfeeding, breast milk sufficiency and exclusive breast feeding in nulliparous women

Public title
Comparison of the effect of acupressure, OKETANI massage and lactation training
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 t0 35 years primipar Ability to speak Persian and be literate No history of breast surgery Exclusive breastfeeding intention Giving birth to a full-term (2500 to 4000 g) healthy baby who is not prohibited from breastfeeding (such as cleft palate, lips and prematurity) Do not take any medication that secondarily disrupts milk production and flow
Exclusion criteria:
Infant hospitalization if breastfeeding is delayed Use fluids other than breast milk to feed the baby The mother's unwillingness to continue participating in the study
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation was done by the The steps of using the software listed were as follows: ETCETERA, Randomization (Random allocation) . Eligible patients are registered by the first author. Envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomaize.com and will be placed inside the envelope. The envelopes will be closed and its contents are not visible from the outside. Then, the purpose of the study is explained to the person who follows the conditions, and the person, if desired, signs the informed consent form and removes an envelope, then opens it and, based on the contents of the envelope, enters into the groups. In this study, individuals will be randomly divided into four groups A (intervention 1), group B (intervention 2), group C (intervention 3) and group D (control) using randomized 8 blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the pre-intervention stage, the questionnaire will be completed by someone other than the Care provider. To blind the methodologist, the group of people will also be hidden from them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahrood University of Medical Sciences
Street address
Shahrood University of Medical Sciences
City
Shahrood
Province
Semnan
Postal code
9717419582
Approval date
2020-09-05, 1399/06/15
Ethics committee reference number
1399.107

Health conditions studied

1

Description of health condition studied
Breast feeding
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Breast feeding
Timepoint
Before the intervention Two weeks after the intervention and one month after the intervention
Method of measurement
Breastfeeding self-efficacy questionnaires, evaluation of infant breastfeeding quality, continuation of exclusive breastfeeding

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Recipient of acupressure. The points used in this group are three points GB21 (at the top of the sternocleidomastoid muscle), point CV17, 4 fingers above the sternum, approximately in the center of the chest) and point CO18 (at the bottom of the indentation) is. Mothers are taught to do these points three times a day for 2 to 5 minutes each time for a total of 14 days.
Category
Treatment - Other

2

Description
Intervention group2: Recipients of OKETANI massage for 30 minutes once a day for 14 days (the first day is done by the researcher and the next days by the mother after the necessary training was given to the mother) in both right and left breasts. In total, it includes 8 hand techniques.
Category
Treatment - Other

3

Description
Intervention group 3: Breastfeeding counseling and training group that receives breastfeeding-related training as soon as possible after delivery and communicating with the baby, as well as for 14 days after delivery by phone or in person if necessary.
Category
Treatment - Other

4

Description
Control group: They only receive routine postpartum care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahar hospital
Full name of responsible person
Niloofar Rabiee
Street address
Shahrood university of medical sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
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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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Niloofar Rabiee
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farzane Karimi
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available