Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of breast massage on exclusive breastfeeding in end of neonatal period and breastfeeding problems in nulliparous mothers after delivery.

Protocol summary

Summary

This study aim to investigate the effect of breast massage to reduce rate of exclusive breastfeeding in the neonatal and maternal breastfeeding problem. Design: A randomized not blinded and just Evaluator didnot information about the type of group and placebo. Setting and conduct: In this study, after obtaining informed consent from nulliparous women, samples will be allocated to intervention and control group according to randomize method, with block size of 4. Before the start of the first breastfeeding postpartum, breast massage will be done for 5 to 10 minutes, and the mothers are recommended to repeat breast massage before each feeding. The control group will be used breastfeeding routine training. Inclusion criteria: having at least primary education, nulliparous women, full consciousness in women after cesarean section, having the healthy and mature baby. Exclusion criteria: having banned diseases breastfeeding mother, mental illnesses of mother, alcoholism, smoking and addiction, twin birth, the mother's underlying disease such as heart disease, patients under treated with radiotherapy. Interventions: breast massage in the intervention group will be done for 5 to 10 minutes before the first breastfeeding after delivery and before any breastfeeding at home. Standard exclusive breastfeeding and breastfeeding problems questionnaire and self-efficacy and perceived stress will be completed after 28 days from delivery. The control group will be used breastfeeding routine training. Also the above mentioned questionnaires will be completed after 28 days from delivery. Finally the percentage of exclusive breastfeeding, breastfeeding problems, the mean score of self-efficacy and perceived stress will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080422407N2**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

Somayeh Ramezani

Name of organization / entity

Shahroud University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2015-08-15, 1394/05/24

Expected recruitment end date

2015-12-15, 1394/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of breast massage on exclusive breastfeeding in end of neonatal period and breastfeeding problems in nulliparous mothers after delivery.

Public title
Breast massage on exclusive breastfeeding and problem breastfeeding
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: having at least primary education, nulliparous women, full consciousness in women after cesarean section, having the healthy and mature baby. Exclusion criteria: having banned diseases breastfeeding mother, mental illnesses of mother, alcoholism, smoking and addiction, twin birth, the mother's underlying disease such as heart disease, patients under treated with radiotherapy.
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Random allocation is done as a block of four. After obtaining informed consent based on breast massage table assigned to intervention and control groups allocated.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud.
City
shahroud
Postal code
3614773955
Approval date
2015-06-20, 1394/03/30
Ethics committee reference number
IR.shmu.rec.1394.46

Health conditions studied

1

Description of health condition studied
Feeding problems
ICD-10 code
P92
ICD-10 code description
Feeding problems of newborn

Primary outcomes

1

Description
Exclusive breastfeeding
Timepoint
28 days after delivery.
Method of measurement
Standard questionnaires breastfeeding

2

Description
Breastfeeding problems
Timepoint
28 days after delivery.
Method of measurement
Questionnaire breastfeeding problems

Secondary outcomes

1

Description
Perceived Stress
Timepoint
28 days after delivery.
Method of measurement
Perceived Stress Questionnaire Sheldon

2

Description
Breastfeeding self-efficacy
Timepoint
28 days after delivery.
Method of measurement
Breastfeeding Self-Efficacy Questionnaire

Intervention groups

1

Description
Intervention groups: breast massage for 5 to 10 minutes before the first lactation researcher and continue doing it before any breastfeeding at home.
Category
Prevention

2

Description
Control group: routine teaching of breast-feeding, after the delivery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiyeh hospital
Full name of responsible person
somayeh ramezani
Street address
Central building of Shahroud University of Medical Sciences,Hafte Tir Square,shahroud
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research; Shahroud University of Medical Sciences
Full name of responsible person
Dr Mohammadhasan Emamian
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Central building ofShahroud University of Medical Sciences,Hafte Tir Square,Shahroud.
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Shahroud
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; Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Somayeh Ramezani
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty