

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 23 3239 7213

##### Email address

s.ramezani@shmu.ac.ir

##### 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,Hafta Tir Square,shahroud

##### City

shahroud

## 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

##### Street address

Central building of Shahroud University of Medical Sciences,Hafta Tir Square,Shahroud.

##### City

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

Shahroud university of medical sciences

##### Full name of responsible person

Somayeh Ramezani

##### Position

Master science of student counseling midwiferys

##### Other areas of specialty/work

##### Street address

Central building of Shahroud University of Medical Sciences,Hafta Tir Square, Shahroud

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##### Phone

+98 23 3239 7213

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S.ramezani82@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahroud university of medical sciences

##### Full name of responsible person

Ahmad Khosravi

##### Position

Faculty member

##### Other areas of specialty/work

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##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shahroud university of medical sciences

##### Full name of responsible person

Somayeh Ramezani

**Position**

Master science of student counseling midwifery

**Other areas of specialty/work**

**Street address**

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**Web page address**

## 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*