

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effect of mother to mother support on breast feeding pattern and breast feeding duration among nulliparous women

#### Protocol summary

##### Summary

Aims: We aimed to assess the effect of support from the mothers with positive breast feeding experience on the patterns and duration of breastfeeding in nulliparous women. Materials and Methods: In this randomized clinical trial, 240 nulliparous women were participated. Convenient sampling was done at hospitals, but the samples were allocated to the intervention (n=120) and control (n=120) groups randomly using Rand and Excel software. The inclusion criteria for the mothers were as follows: willingness to participate, nulliparity, singleton pregnancy, residing in Ilam, being available and literate, gestational age of over 37 weeks at the time of delivery, no diagnosed debilitating disease in the mother or neonate, no fetal disorders during pregnancy, not requiring NICU stay. The control group program included the Routine trainings. The intervention group program included the Routine trainings plus the support from the 30 mothers with positive breast feeding experience during the 3 months after delivery. Breast feeding patterns in the end of first, second and third months and Mother's satisfaction from breastfeeding was evaluated in the end of third month.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080735540N1**

Registration date: **2017-10-07, 1396/07/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-07, 1396/07/15

##### Registrant information

##### Name

Hashemieh Chehreh

##### Name of organization / entity

School of Nursing & Midwifery, Shahid Beheshti University of Medical Science,

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5366

##### Email address

hashemieh\_chehreh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences and Ilam's Red Crescent Society

##### Expected recruitment start date

2009-06-22, 1388/04/01

##### Expected recruitment end date

2010-04-19, 1389/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of mother to mother support on breast feeding pattern and breast feeding duration among nulliparous women

##### Public title

breast feeding and support

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

The inclusion criteria for the mothers were as follows: willingness to participate, nulliparity, singleton pregnancy, residing in Ilam, being available and literate,

gestational age of over 37 weeks at the time of delivery, no diagnosed debilitating disease in the mother or neonate, no fetal disorders during pregnancy, not requiring NICU stay. The inclusion criteria for the peer support were as follows: willingness to participate, residing in Ilam, being available and literate, Have a successful breastfeeding history, no diagnosed debilitating disease. Exclusion criteria: Mothers not available for telephone counseling.

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 240

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Assigning samples to the groups by blocking method was done using the Random function and using Excel software

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Science

**Street address**

Velengak, Tehran

**City**

Tehran

**Postal code****Approval date**

2009-07-13, 1388/04/22

**Ethics committee reference number**

25-12-3535

**Health conditions studied****1****Description of health condition studied**

breast feeding

**ICD-10 code**

p92.5

**ICD-10 code description**

Suppressed lactation

**Primary outcomes****1****Description**

Breastfeeding Patterns and Duration

**Timepoint**

The end of the first, second and third months

**Method of measurement**

evaluation of Breastfeeding Patterns and Duration

**Secondary outcomes****1****Description**

Mother's satisfaction from breastfeeding

**Timepoint**

the end of third month

**Method of measurement**

Lactation Satisfaction Form

**Intervention groups****1****Description**

The phone number, address and name of at most 8 nulliparous mothers were given to two supporters with similar age, education status, socio-economic level, and residential area. The supporter called the mothers within 48 hours after discharge to introduce herself. Then, in the next phone calls and during the next 3 months. The mother's call was unlimited and based on her need and she could call the supporter at any desired time. Moreover, the supporter called the mothers every week and encouraged them to continue exclusive breastfeeding. Question and answer sessions were also held in the presence of the supporters and the authors every two weeks during the first, second, and third months of study in the Red Crescent Society office in Ilam.

**Category**

Other

**2****Description**

The control group program included the Routine trainings. The intervention group program included the Routine trainings plus the support from the 30 mothers with positive breast feeding experience during the 3 months after delivery

**Category**

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahide Mostafa Khomeini Hospitals

**Full name of responsible person**

Nursing Head Nursing

**Street address**

Shahide Mostafa Khomeini Hospital, Ilam

**City**

Ilam

### 2

#### Recruitment center

**Name of recruitment center**

Ghaem Hospitals

**Full name of responsible person**

Nursing Head Nursing

**Street address**

Ilam- Ghaem hospitals

**City**

Ilam

### 3

#### Recruitment center

**Name of recruitment center**

Kowsar hospitals

**Full name of responsible person**

Nursing Head Nursing

**Street address**

Kowsar Hospitals, Ilam

**City**

Ilam

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ilam's Red Crescent Society

**Full name of responsible person**

The mannager

**Street address**

22 Bahman Square, Ilam

**City**

Ilam

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ilam's Red Crescent Society

**Proportion provided by this source****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*

### 2

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Faculty of Nursing and Midwifery Shahid Beheshti

**Full name of responsible person**

Dr Yaghemaee

**Street address**

Valiasr St., Nursing College Campus, Nursing Midwifery Faculty, Tehran, Iran

**City**

Tehran

**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 of Faculty of Nursing and Midwifery Shahid Beheshti

**Proportion provided by this source****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**

Ilam University of Medical Science

**Full name of responsible person**

zolaykha karamolahi

**Position**

ms

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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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*