

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The Effect breastfeeding counseling on self- efficacy and maintaining breastfeeding among primiparous mothers attending to Fatemieh Hospital of Hamadan

#### Protocol summary

##### Summary

This is a single blind intervention study that will be done on 110 nulliparous women admitted to hospital after delivery. Tools using in this study will be demographic and self-efficacy questionnaires and a breastfeeding checklist that will be given to the individuals who wishing to participate in the study. A random sampling will be selected participants in two groups. In even days intervention group and in odds days control group will be selected. Intervention group will receive a face to face training on breastfeeding 30 minutes after delivery. Control group will receive routine hospital program. The other sections of intervention will be delivered on first day before women's discharge from hospital and 7 days after delivery using a face to face training and an instructed package includes a CD and a Pamphlet. After four months, the breastfeeding self-efficacy score, mother's knowledge and practice will be measured using checklist and questionnaires by home visiting the subjects. Then the self-efficacy score, knowledge and practice in intervention group will be compared with control group. For data analysis, SPSS software, version 16 will be used.

#### General information

##### Acronym

Breastfeeding-Counseling-Self efficacy

##### IRCT registration information

IRCT registration number: **IRCT2015021610426N6**

Registration date: **2015-03-04, 1393/12/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-03-04, 1393/12/13

#### Registrant information

##### Name

Parisa Parsa

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1822 4396

##### Email address

parsa@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Hamadan University of Medical Sciences

#### Expected recruitment start date

2015-04-04, 1394/01/15

#### Expected recruitment end date

2016-04-03, 1395/01/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect breastfeeding counseling on self- efficacy and maintaining breastfeeding among primiparous mothers attending to Fatemieh Hospital of Hamadan

#### Public title

The Effect breastfeeding counseling on self- efficacy and maintaining breastfeeding among primiparous mothers attending to Fatemieh Hospital of Hamadan

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: primiparity; having a healthy newborn; singleton pregnancy; having at least basic literacy; without history of formal education about breastfeeding; without high risk Conditions; No smoking mothers; Living in Hamadan; having a valid phone number; completed consent form to participate of the study. Exclusion criteria: mother or infant conditions, illness and stressful events during the study that breastfeeding is contraindicated; changing the residency.

#### **Age**

From **15 years** old to **45 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **110**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single 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 Hamadan University of Medical Sciences

##### **Street address**

Hamadan University of Medical Sciences- Shahid Fahmideh Street- Counterpoint of Mardom Park- Hamadan

##### **City**

Hamadan

##### **Postal code**

65178

#### **Approval date**

2015-02-09, 1393/11/20

#### **Ethics committee reference number**

p/16/35/9/5856

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Disorders of lactation

#### **ICD-10 code**

O92.7

#### **ICD-10 code description**

Other and unspecified disorders of lactation

### **Primary outcomes**

#### **1**

#### **Description**

Mother's self-efficacy on breastfeeding

#### **Timepoint**

half an hour, first day, seventh day and four months after delivery

#### **Method of measurement**

Self-efficacy questionnaire

### **Secondary outcomes**

#### **1**

#### **Description**

Maintaining of exclusive breastfeeding

#### **Timepoint**

first day, seventh day and four months after delivery

#### **Method of measurement**

Checklist of breastfeeding

### **Intervention groups**

#### **1**

#### **Description**

Intervention group will receive a face to face training 30 minuets after delivery. The other sections of intervention will be delivered in the first day after delivery before women's discharge from hospital and 7 days after delivery in hospital using a face to face training and an instructed package includes a CD and a Pamphlet. After four months, the breastfeeding self-efficacy score, mother's knowledge and practice will be measured using checklist and questionnaires by home visiting the subjects.

#### **Category**

Behavior

#### **2**

#### **Description**

Control group will receive routine post- partum program. 30 minuets after delivery, at first day before women discharge from hospital and 7 days after delivery and four months after delivery the breastfeeding self-efficacy score, mother's knowledge and breastfeeding practice will be measured using checklist and questionnaires by home visiting the subjects

#### **Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Fatemieh Hospital of Hamadan

**Full name of responsible person**

Dr. Nahid Radnia

**Street address**

Fatemieh Hospital of Hamadan, Kermanshah street-  
Hamadan

**City**

Hamadan

Shahid Fahmideh Street- Counterpont of Mardom  
Park- Hamadan

**City**

Hamadan

**Postal code**

65178-38698

**Phone**

+98 81 3838 0150

**Fax**

**Email**

parsa@umsha.ac.ir

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Saied Bashirian

**Street address**

Hamadan University of Medical Sciences- Shahid  
Fahmideh Street- Counterpoint of Mardom Park-  
Hamadan

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Hamadan 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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Asistant Professor / PhD

**Other areas of specialty/work**

**Street address**

Research Center for Chronic Diseases Home Care,  
Hamadan University of Medicine and Health Sciences,

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Assistant Professor/Ph.D

**Other areas of specialty/work**

**Street address**

Research Center for Chronic Diseases Home Care,  
Hamadan University of Medicine and Health Sciences,  
Shahid Fahmideh Street- Counterpont of Mardom  
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## Person responsible for updating data

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**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Assistant Professor/ Ph.D

**Other areas of specialty/work**

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**Postal code**

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+98 81 3838 0150

**Fax**

**Email**

parsa@umsha.ac.ir

**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*