

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

#### Protocol summary

##### Summary

Objective: This study aims at determine the effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant is designed, 2014. Exclusion criteria: Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions. Methods: This is quasi-experimental study of two groups. The target population of this study consists of all mothers and hospitalized premature infants. Sample size of 62 patients in the intervention group and 62 patients in the control group are determined. Sampling is done by random permutation block. In order to continue exclusive breastfeeding and breastfeeding counseling intervention in preterm infants during the five sessions by the researcher, daily during hospitalization for direct instruction and individual face to face, the theoretical and practical on the steps of reproductive health service (Using the replica, pamphlets, educational compact Disk training) and incentive packages and daily goals chart will be performed. But the control group will performed routine care. Data collection tools included three questionnaires to assess knowledge of mothers about breastfeeding; Training based on structural BASNEF model, demographic characteristics, check list observation and consultation performance breastfeeding mothers, and scales weighing children's model co12000 is made in Iran.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014111013405N6**

Registration date: **2015-01-05, 1393/10/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-05, 1393/10/15

##### Registrant information

###### Name

Seyyedeh Zahra Masoumi

###### Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0150

###### Email address

zahra.masoomi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamedan University of Medical Sciences

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-05-22, 1394/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

##### Public title

The effect of counseling on breast feeding in preterm infants

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Mother are literate; Mother prevention of adduction; Not having a mother with underlying disease and gestational diabetes and preeclampsia; Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Mother's unwillingness to cooperate; Metabolic disorders in newborns; Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions; Mothers taking antidepressant drugs and psychotropic substances; The inability of the breast feeding at the discretion of the physician; Infectious disease of the breast; Unavailability of the mother at the time of completing of questionnaires test and attending breastfeeding education classes during pregnancy.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **124**

**Randomization (investigator's opinion)**

Randomized

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

Not 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 Hamedan university of Medical Sciences

**Street address**

Vice Chancellor of Research and Technology,  
Hamedan University of Medical Sciences, Shahid  
Fahmideh Avenue, Hamedan

**City**

Hamedan

**Postal code**

6516645977

**Approval date**

2014-11-25, 1393/09/04

**Ethics committee reference number**

16/35/9/4125/پ

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

Relationship counseling to exclusive breastfeeding continuation in mothers with hospitalized preterm infant

**ICD-10 code**

p05-p06-p0

**ICD-10 code description**

Disorders related to length of gestation and fetal growth

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

exclusive breastfeeding continuation

**Timepoint**

Before then once monthly until 4 months after birth

**Method of measurement**

Check list

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

Birth weight

**Timepoint**

Before then once monthly until 4 months after birth

**Method of measurement**

Weighing Scales babies

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

Intervention group: breastfeeding counseling for continued exclusive breastfeeding in preterm infants during 5 session by researcher, daily during hospitalization direct instruction and individual face to face, the practical and theoretical will be performed.

**Category**

Prevention

**2****Description**

Control group: regular and ongoing training by personnel neonatal unit and after delivery to receive.

**Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Fatemieh Hospital

**Full name of responsible person**

**Street address**

**City**

Hamedan

Hamedan

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zahramid2001@yahoo.com;  
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**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for Research the Technology,  
Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeed Bashiriyan

**Street address**

HVice Chancellor of Research and Technology,  
Hamedan University of Medical Sciences, Shahid  
Fahmideh Avenue, Hamedan

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Hamedan

**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 the Technology, Hamedan  
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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Seyedeh Zahra Masoomi

**Position**

Phd in reproductive health, Vice chancellor for the  
School of Nursing and Midwifery

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Hamedan University  
of Medical Sciences, Shahid Fahmideh Avenue,

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Dr Seyedeh Zahra Masoomi

**Position**

Ph.D of reproductive health

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## Person responsible for updating data

### Contact

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Hamedan University of Medical Sciences

**Full name of responsible person**

Shiler Ahmadi

**Position**

Bachelor of Midwifery/ Student of Master in Midwifery  
Counselling

**Other areas of specialty/work**

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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*