Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamadan University of Medical Sciences

Full name of responsible person
Dr. Saied Bashirian

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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
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Full name of responsible person
Dr. Parisa Parsa

Position
Asistant Professor / PhD

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