

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial to compare the effect of receiving and not receiving a family-centered empowerment program on breast feeding mothers

Protocol summary

Summary

Objectives: This clinical trial has been designed to evaluate the effect of family-centered empowerment program on breast feeding mothers. The study population will be mothers who refer to selected Isfahan health centers. Mothers randomly will be divided into two groups, one group is control (without training) and another be intervention (with training and consultation). Sample size according to the sample size formula and expected effectiveness, is thirty six families in each group. This study is a single blind clinical trial for participants in the intervention and control groups. **Inclusion criteria:** mothers with age over eighteen years old, gestational age thirty two to thirty six weeks, singleton pregnancy, low-risk pregnancy with a desire to participate in the research, be able to understand and complete the questionnaire and absence of spiritual and mental disorders. **Exclusion criteria:** lack of desire to continue cooperation at any stage of research. **Design:** With available sampling, gradually selected pregnant women eligible inclusion criteria and randomly placed in the intervention and control groups. **Intervention:** in intervention group, two educational sessions (breastfeeding importance and techniques, the prevention and treatment of breast feeding problems and...) will be held during pregnancy and one breastfeeding consultation session after birth for mothers and key members of her family. The control group will not receive any training. Two weeks and two months after birth, main outcome will be measured include mother's empowerment in breastfeeding and breastfeeding sufficiency through mothers point of views will be evaluated by the questionnaire in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723657N1**

Registration date: **2015-11-16, 1394/08/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-16, 1394/08/25

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare the effect of receiving and not receiving a family-centered empowerment program on breast feeding mothers

Public title

The Effectiveness of family-centered empowerment program on breast feeding mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: mothers over eighteen years, gestational age thirty two to thirty six weeks, singleton pregnancy, low-risk pregnancy with a desire to participate in the research, be able to understand and complete the questionnaire and lack of spiritual and mental disorders. Exclusion criteria include lack of desire to continue cooperation at every stage of research

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **72**

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 Isfahan University of Medical Sciences

Street address

Nursing and Midwifery Faculty, Isfahan University of Medical Sciences, Hezarjerib St.

City

Isfahan

Postal code

Approval date

2014-05-22, 1393/03/01

Ethics committee reference number

393472

Health conditions studied

1

Description of health condition studied

breastfeeding

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Mother's empower in breastfeeding

Timepoint

Two weeks & two months after birth

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Breastfeeding sufficiency in mothers point of views

Timepoint

Two weeks & two months after birth

Method of measurement

Questionnaire

Intervention groups

1

Description

Two sessions (breastfeeding importance and techniques, the prevention and treatment of breast feeding problems and...) in pregnancy period and one breastfeeding consultation session after birth for mothers and key members of her family. Training methods are lecture, question and answer, playing movie, book introduction and support

Category

Behavior

2

Description

Control group will not receive training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Health and Treatment Center

Full name of responsible person

Zeinab Heidari

Street address

Shohada Sq.

City

Isfahan

2**Recruitment center****Name of recruitment center**

Navab Health and Treatment Center

Full name of responsible person

Zeinab Heidari

Street address**City**

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice Chancellor for Research, Isfahan University of
Medical Sciences**Full name of responsible person**

Mahdi Neamatbakhsh

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Isfahan University of Medical Sciences, Hezarjerib St.

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

Yes

Title of funding sourceVice Chancellor for Research, Isfahan 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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Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty