

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison the Effect of Two Methods of Breastfeeding Education with and without Grandmothers Attendance on Breastfeeding Self-Efficacy and Infant Feeding Pattern in Nulliparous Women

Protocol summary

Study aim

Determine the effect of two methods of Breastfeeding Education with and without the presence of Grandmothers on Breast feeding self-efficacy and infant feeding pattern in Nulliparous women

Design

Semi experimental study with control group, continuous sampling, with two parallel groups design of 70 patients.

Settings and conduct

This study will be conducted in the Breastfeeding Education class of Amirmomenin Hospital. The content of educational materials in pregnancy in accordance with the standard country guidelines and twice in pregnancy in divided sections will be presented by Speech method. Pamphlet with colored images containing Breastfeeding material will be given to participants in Breastfeeding Education classes. Misconceptions about mother's milk and facts will be presented to maternal grandmothers with colored pamphlets. After delivery, Summary of Breastfeeding Educations presented in Pregnancy will be repeated, the film of healthy baby will be shown routine in the country and will be given help to the mother in breastfeeding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nullipara, low risk pregnancy, Singleton pregnancy, healthy fetus, 31week of gestational age and the absence of psychological disorders in Grandmother. exclusion criteria: Absent in breast feeding education class more than one session, The maternal grandmother is not caregiver of the mother after childbirth.

Intervention groups

In the intervention group, Nulliparous women Along with her mothers will attend in Breastfeeding Education classes , but in the control group, Nulliparous women will attend the classes alone.

Main outcome variables

Breastfeeding self-efficacy and infant feeding pattern.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N1**

Registration date: **2018-06-12, 1397/03/22**

Registration timing: **prospective**

Last update: **2018-06-12, 1397/03/22**

Update count: **0**

Registration date

2018-06-12, 1397/03/22

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Two Methods of Breastfeeding Education with and without Grandmothers Attendance on Breastfeeding Self-Efficacy and Infant Feeding Pattern in Nulliparous Women

Public title

Effect of Grandmothers Breastfeeding Education on Breastfeeding in Nulliparous Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality understand and speak to Persian nullipara Singleton pregnancy low risk pregnancy 18-35 years old 31-34 week of gestational age healthy fetus without congenital malformation lack of contraindication of lactation the absence of psychological disorders in the neonate maternal grandmother delivery in Amirmomenin Hospital.

Exclusion criteria:

Absent in breast feeding education class more than one session The maternal grandmother is not caregiver of the mother after childbirth.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Iran University of Medical

Street address

Hemmat Highway - next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.IUMS.FMD.REC. 1396.9511373007

Health conditions studied

1

Description of health condition studied

Breast feeding Education in pregnant women with the attendance of grandmothers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The difference in Breast feeding self-efficacy with 13-item Breast feeding self-efficacy tool in two groups: control and intervention

Timepoint

Determine the Breast feeding self-efficacy score at the time of discharge from the hospital, 4 weeks later and 8 weeks after delivery

Method of measurement

13-item Breast feeding self-efficacy tool

2

Description

Differences in the frequency of infant feeding patterns in two groups of control and intervention

Timepoint

Frequency of infant feeding patterns at 4 and 8 weeks postpartum

Method of measurement

Mother-phone questioning about infant feeding patterns

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participation of Nulliparous Women in Breastfeeding Education classes without Attendance of Grandmothers

Category

Other

2

Description

Intervention group: Participation of Nulliparous Women in Breastfeeding Education classes with Attendance of Grandmothers

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Gharaei Tayebeh

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Nazi Abad, Shahid Shir Mohammadi Street, opposite Sardar Forest Park

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Tayebah Gharaei

Position

Student

Latest degree

Bachelor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available