Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Effect of Two Methods of Breastfeeding Education with and without Grandmothers Attendence 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 Amiralmomenin 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)

Phone

+98 21 4365 1139

Email address

l.amirifarahani@gmail.com

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 Attendence 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 Amiralmomenin 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 attendence 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 Attendence of Grandmothers
Category
Other

2

Description

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

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Gharaei Tayebeh

Street address

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

City

Tehran

Province

Tehran

Postal code

1811694784

Phone

+98 21 5534 6210

Fax

+98 21 5534 6301

Email

tayebeh.gharaei@gmail.com

Web page address

https://mail.google.com/mail/u/0/#inbox/1631af5558c7e9b0?compose=163ac5efd6482d74

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakouti

Street address

Shahid Hemmat highway, District 2

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6650 9024

Fax

+98 21 8805 2248

Email

malakoutik@yahoo.com

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

Tayebeh Gharaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Rashid Yasemi

City

Tehran

Province

Tehran

Postal code

1744943683

Phone

+98 21 7740 6278

Email

tayebeh.gharaei@gmail.com

Web page address

https://mail.google.com/mail/u/0/#inbox/1631af5558c7e9b0?compose=163ac5efd6482d74

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Gharaei Tayebeh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Rashid Yasemi

City

Tehran

Province

Tehran
Postal code
1744943683
Phone
+98 21 7740 6278
Email
tayebeh.gharaei@gmail.com
Web page address
https://mail.google.com/mail/u/0/#inbox/1631af5558c7e9b0?compose=163ac5efd6482d74

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Rashid Yasemi
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1139
Email
l.amirifarahani@gmail.com
Web page address

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