Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Determining the impact of training on postpartum mother self efficacy in breast feeding process

Protocol summary

Study aim
Determining The effect of education on mothers' self-efficacy in breastfeeding process

Design
This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 70 people in each group.

Settings and conduct
The study will be conducted at Kamali Hospital on pregnant women. Patients who signed informed consent will be randomly divided into two groups. The first group will receive breast feeding education through lectures . The second group will not receive any intervention. Participants' self-efficacy is measured by a questionnaire before and after the intervention . The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnancy; the fetus should not have any complications on ultrasound, without communication or hearing problems; pregnancy without complication; without possibility of premature birth. Exclusion criteria: history of preterm labor gestational age over 34 weeks; medical complication that affects breastfeeding; fetal abnormalities; the mother does not accept exclusive breastfeeding; nipple retraction or anatomical problem of the breast; hospitalization of mother and infant; pregnancy by assisted reproductive technology.

Intervention groups
Intervention group: breastfeeding topics are taught in 4 40-minute sessions through lectures. In 28, 30, 32 and 34 weeks of pregnancy. The first session on the benefits of breast milk. The second session: breast problems. Session 3: Risks of bottle-feeding. Session 4: child-friendly hospitals and a summary of previous sessions. Control group: without intervention.

Main outcome variables
Self-efficacy in knowing the benefits of breastfeeding
Self-efficacy in proper breastfeeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210915052481N1**
Registration date: **2021-10-16, 1400/07/24**
Registration timing: **prospective**

Last update: **2021-10-16, 1400/07/24**
Update count: **0**

Registration date
2021-10-16, 1400/07/24

Registrant information

Name
Fateme Shirpak
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 26 3455 7514
Email address
shirpakfateme@vatanmail.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Determining the impact of training on postpartum mother self efficacy in breast feeding process

Public title
The effect of training on self-efficacy in breastfeeding process

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnancy The fetus should not have any complications on ultrasound Without communication or hearing problems Pregnancy without complication There is no possibility of premature birth
Exclusion criteria:
History of preterm labor Gestational age over 34 weeks Medical complication that affects breastfeeding Fetal abnormalities The mother does not accept exclusive breastfeeding Nipple retraction or anatomical problem of the breast Hospitalization of mother and infant Pregnancy by assisted reproductive technology

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Our sample size is 140 people, with 70 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 4.

Blinding (investigator's opinion)
Single blinded

Blinding description
140 cards containing sequences of treatments will be written and a10-digit random code, as the patient’s identification number, will be provided for each packet. When the researcher announces the eligibility of a patient, the methodologist will provide the researcher with the envelope. The person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. Data analysis will be carried out by a statistician who is aware of all the processes performed.the participants are aware of the type of intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
City
Karaj
Province
Alborz
Postal code
3149779453

Approval date
2021-08-25, 1400/06/03

Ethics committee reference number
IR.ABZUMS.REC.1400.141

Health conditions studied

1

Description of health condition studied
Breast feeding

ICD-10 code
P92.5

ICD-10 code description
Neonatal difficulty in feeding at breast

Primary outcomes

1

Description
Self-efficacy in knowing the benefits of breastfeeding

Timepoint
Before and after intervention

Method of measurement
Dennis Standard Questionnaire

2

Description
Self-efficacy in proper breastfeeding

Timepoint
Before and after intervention

Method of measurement
Dennis Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: breast-feeding topics are taught in 4 40-minute sessions through lectures. In 28, 30, 32 and 34 weeks of pregnancy. The first session : the benefits of breast milk. The second session: breast problems. Session 3: Risks of bottle-feeding. Session 4: Child-friendly hospitals and a summary of previous sessions.
Category
Prevention

2

Description
Control group: no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali hospital
Full name of responsible person
Fateme shirpak
Street address
Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3455 7514
Email
Shirpakfateme@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Nourisepehr
Street address
Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
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Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Fateme shirpak
Position
Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
Street address
Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3222 2021
Email
Shirpakfateme@vatanmail.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Fateme shirpak
Position
Midwifery
Latest degree
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Other areas of specialty/work
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Postal code
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+98 26 3222 2021
Email
Shirpakfateme@vatanmail.ir

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Fateme shirpak
Position
Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available