

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 a 10-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

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

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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;
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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

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Karaj University of Medical Sciences

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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