Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of health promotion based on the Pender model on breastfeeding self-efficacy and mother-infant attachment in primiparous mothers of

Protocol summary

Study aim

To determine the effect of health promotion education based on the Pender model on breastfeeding self-efficacy and mother-infant attachment in primiparous mothers at Shohada Hospital in Behshahr city in 1403.

Design

The research sample will be selected using the available sampling method. The research unit will also be given written and verbal assurance that during the study, if they do not wish to continue participating in the study, they can withdraw from the study. It will also be explained to the mothers that they may be randomly assigned to the test or control group, and that the control group will not be deprived of education, and breastfeeding education will be provided to them according to the hospital's breastfeeding support routine. After obtaining informed consent, random allocation will be made to two control and test groups using a simple method using the website. The sample size in this study was calculated as 50 people using G power software .

Settings and conduct

This experimental study is a pre-test and post-test type with two control and test groups., the researcher introduces himself to the authorities of the Behshahr City SHohada Hospital.

Participants/Inclusion and exclusion criteria

All primiparous mothers

Intervention groups

Training sessions will be held for 6 sessions (based on needs assessment, individually and in groups. In the group training section, 30-minute training sessions will be provided based on the Pender Health Promotion Model in proportion to the dimensions of health-promoting behaviors, including diet, physical activity, feeling responsible for personal health, attention to spiritual growth, interpersonal relationships, and stress management .

Main outcome variables

Breastfeeding-based health promotion, breastfeeding self-efficacy, mother-infant attachment

General information

Reason for update

Acronym

خودکارآمدی شیردهی

IRCT registration information

IRCT registration number: **IRCT20250603066048N1**
Registration date: **2025-07-31, 1404/05/09**
Registration timing: **retrospective**

Last update: **2025-07-31, 1404/05/09**
Update count: **0**

Registration date

2025-07-31, 1404/05/09

Registrant information

Name

razie ezzatpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3453 5104

Email address

razie.ezp70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-04, 1404/03/14

Expected recruitment end date

2025-07-05, 1404/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of health promotion based on the Pender model on breastfeeding self-efficacy and mother-infant attachment in primiparous mothers of

Public title
Effect of health promotion based on the Pender model on breastfeeding self-efficacy and mother-infant attachment in primiparous mothers

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
primiparous mothers Singleton babies

Exclusion criteria:
Having an underlying medical condition in the mother multiple mother Drug addiction

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to assign randomly, each of the samples was given a numbering code and the numbers will be placed in an envelope. For randomization, a random number table is used, which has 99 rows and columns, and the row and column numbers are arranged in five-digit blocks next to each other and in a separated manner. In order to use the random number table, first start by reading the table numbers, predetermined (in the row or column direction). The point selection is done by closing the eyes and placing a finger or pen tip on the table and unconsciously encountering two types of numbers. Then odd numbers are assigned to group A and even numbers to group B. The researcher places his hand on one of the numbers in the table and moves upwards and records the numbers in one of the groups A and B. depending on whether they are even or odd. Finally, one of the groups is randomly selected as the intervention group and the other as the control group.

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
Islamic Azad University, Aliabad Katul Branch

Street address
University Boulevard

City
Ali Abad katoul

Province
Golestan

Postal code
کدپستی: 93451-49417

Approval date
2025-06-01, 1404/03/11

Ethics committee reference number
IR.IAU.AK.REC.1404.006

Health conditions studied

1

Description of health condition studied
Pender Model Health Promotion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Breastfeeding self-efficacy

Timepoint
Before and after the intervention in the experimental and control groups

Method of measurement
Breastfeeding self-efficacy questionnaire

Secondary outcomes

1

Description
Mother-infant attachment

Timepoint
Before and after the study in the experimental and control groups

Method of measurement
Mother-infant attachment questionnaire

Intervention groups

1

Description
Intervention group: Then, training sessions will be held individually and in groups for 6 sessions (three times a week) based on needs assessment. In the individual training phase, training will be given according to the mothers' individual needs and their questions will be answered based on previous experiences, education level and social status. After the intervention, the test group will complete the Dennis Breastfeeding Self-Efficacy Questionnaire and the Muller Mother-Infant Attachment Questionnaire again.

Category
Lifestyle

2

Description
Control group In the control group, they will also receive routine interventions and training from the ward and will not be released. In order to ensure faimess, educational materials will be provided to the control group after the end of the study so that they too can benefit from this intervention

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
SHohada Hospital

Full name of responsible person
Razie Ezzatpanah

Street address
Mahdie Ave.

City
Behshar

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Mazandaran

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4851799551

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Razie.ezp70@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Aliabad katoul

Full name of responsible person
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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
The University of Aliabad katoul

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
Islamic Azad University

Full name of responsible person
Razie Ezzatpanah

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Omitting part of the data, such as information related to the main outcome
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Without conditions
From where data/document is obtainable
razie-ezp70@gmail.com
What processes are involved for a request to access data/document
No duration
Comments