

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of need-based education in comparison with conventional education on breastfeeding self-efficacy and behavior of primiparous.

Protocol summary

Study aim

Determining the effect of need-based education on self-efficacy and breastfeeding behavior in primiparous women

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 2 on 70 patients. For randomization, the names of the centers will be written on some balls and placed inside a bag and in the other bag the intervention and control groups' name will be placed. Then one ball will be drawn from each bag to determine which group will be allocated to which center

Settings and conduct

1- Study place: Najafi, Villa, Hazrat Rasool and Imamat health centers, which are a subset of health center No. 1 in Mashhad. 2- Study population: Women in the first 34 weeks of labor. 3- In this study, blindness was not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age of 34 weeks; being primiparous. Non-inclusion criteria: medical problems; midwifery problems; anatomical defects and breast surgery.

Intervention groups

In the intervention group, by completing the need assessment form, the educational needs of the research unit are determined. Then, the relevant tutorials are sent to them in the form of video, image and pamphlet in cyberspace. after the intervention and four weeks after delivery, questionnaire will be completed by mothers. The control group will receive routine training at the health center.

Main outcome variables

Breastfeeding self-efficacy; Breastfeeding behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211217053433N1**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Ailin Azadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3868 8433

Email address

azadiana981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of need-based education in comparison with conventional education on breastfeeding self-efficacy and behavior of primiparous.

Public title

The effect of need-based education on breastfeeding behavior and self-efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All primiparous mothers at 34 weeks of gestation

Exclusion criteria:

Reluctance to participate in the study Not being Iranian multiparity Multiplication intrauterine growth restriction Study in medical sciences, psychology and counseling Existence of depression, anxiety and stress Existence of midwifery problems and high-risk cases Age under 18 and over 35 years Gestational age more or less than 34 weeks Existence of medical disease Reluctance to breastfeeding Lack of access to smart phones Existence of anatomical defects and breast surgery Lack of minimum literacy (writing and reading ability)

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

Randomization using spheres and bags. There are four balls with the names of four health centers in one bag and four balls with two intervention numbers and two control numbers in the other bag. At the same time, one ball will be drawn from each bag to determine which group will be allocated to which center

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 the School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery, Ebn_e_sina Ave, Daneshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.080

Health conditions studied**1****Description of health condition studied**

Breastfeeding behavior and self-efficacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Breastfeeding self-efficacy

Timepoint

At the beginning of the study and four weeks after delivery

Method of measurement

Breastfeeding self-efficacy questionnaire

Secondary outcomes**1****Description**

Breastfeeding behaviour

Timepoint

Four weeks after delivery

Method of measurement

IBFAT questionnaire

Intervention groups**1****Description**

Intervention group: Breastfeeding training based on needs assessment questionnaire and virtual training in the form of videos, pamphlets and pictures in four to six 45 to 60 minute sessions

Category

Other

2**Description**

Control group: Receiving routine training at the health center

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center number 1

Full name of responsible person

Dr. Baratali Arabnezhad

Street address

Between Vakilabad 66 and 68

City

Mashhad

Province

Razavi Khorasan

Postal code

9179793945

Phone

+98 51 3501 8011

Email

pr@mums.ac.ir.hc1

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Daneshgah Street; Mashhad University of Medical Sciences.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3841 2081

Email

Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahin Tafazoli

Position

Assistant professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of nurse and midwifery, Ebn_e_sina Ave, Daneshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Tafazzolim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahin Tafazoli

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of nurse and midwifery, Ebn_e_sina Ave, Daneshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Tafazzolim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ailin Azadian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery; Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91897-63898

Phone

+98 51 3522 3446

Email

Azadiana981@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be shared after participants become unrecognizable

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All researchers

Under which criteria data/document could be used

Currently unknown

From where data/document is obtainable

Sending email to Azadiana981@mums.ac.ir or attending Library of Mashhad School of Nursing to Mashhad, Daneshgah St.

What processes are involved for a request to access data/document

First, sending a requested through email or attending the library of Mashhad School of Nursing in the case of not receiving any response within a week

Comments