

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigating the effect of using breastfeeding application and face-to-face training on breastfeeding self-efficacy and weighing neonates of prime parous mothers

Protocol summary

Self-efficacy, baby weighing, amount of exclusive feeding

Study aim

Comparison of training through the application and face-to-face training with the usual method on the self-efficacy of mothers breastfeeding and weighing the baby

Design

The current research is a phase 2 randomized clinical trial with two intervention groups, training through software and face-to-face training with parallel groups without blinding and a control group receiving routine training in health centers, the study sample through group allocation) sample selection includes 144 people in each group, 48 people is

Settings and conduct

Sampling from 3 nearby health centers face-to-face training group: information according to the standard training courses of the Ministry of Health was prepared in the form of PowerPoint and during 4 sessions from week 35 to 37 and one session 3-5 days later It will be provided to mothers from childbirth. 2- Application group: First, the application will be designed and evaluated, and during a 15 to 30-minute session, it will be installed on mobile phones and how to use it will be explained to mothers. 3- Routine training of the health center. will be found) in all three groups at 15 days at the end of the first month and at the end of the second month after birth, using a scale and weighing the baby and the standard Dennis breastfeeding self-efficacy questionnaire and the exclusive breastfeeding checklist will be done

Participants/Inclusion and exclusion criteria

There is no harm

Intervention groups

Face-to-face training during 4 sessions from 35 to 37 weeks and 3 to 5 days after delivery 2- The application will be installed and trained on Hamran's phone during a 20-30 minute session 3- Control group: routine care

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230729058965N1**

Registration date: **2023-09-19, 1402/06/28**

Registration timing: **prospective**

Last update: **2023-09-19, 1402/06/28**

Update count: **0**

Registration date

2023-09-19, 1402/06/28

Registrant information

Name

Fateme Baluch

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

balouchf4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using breastfeeding application and face-to-face training on breastfeeding self-efficacy and weighing neonates of prime parous mothers

Public title

The effect of breastfeeding education with face-to-face application on mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent singleton pregnancy term healthy baby weight more than 2500 no dependence on drugs mother's lack of education in fields related to medicine ability to use a mobile phone no prohibition of breastfeeding

Exclusion criteria:

The unwillingness of the mother to cooperate and admit the baby to the intensive care unit absence of more than one session in breastfeeding counseling sessions the death of the baby and the occurrence of unfortunate events in the family (death, accident and illness) and the inability to use the application in the follow-up The next ones

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this research is group allocation in such a way that the study sample is randomly selected from health centers number 5, 4, 3, 2, 1 and 2, and one center is selected from the health centers under the collection of these bases and to be homogeneous. The samples will be selected from two centers adjacent to this health center and sampling will be done by simple randomization. (due to lack of communication between trainees)

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 Mashhad University of Medical Sciences

Street address

Ferdowsi University, Faculty of Nursing and Midwifery, Vakil Abad Boulevard, Mashhad

City

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Razavi Khorasan

Postal code

9137913199

Approval date

2023-09-16, 1402/06/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.071

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

Breastfeeding education, breastfeeding problems and breastfeeding self-efficacy

ICD-10 code

P92Feeding

ICD-10 code description

P92.0Vomiting in newbornP92.1Regurgitation and rumination in newbornP92.2Slow feeding of newbornP92.3Underfeeding of newbornP92.4Overfeeding of newbornP92.5Neonatal difficulty in feeding at breastP92.8Other feeding problems of newbornP92.9Feeding problem

Primary outcomes**1****Description**

Breastfeeding self-efficacy is the mother's perceived ability to breastfeed her infant

Timepoint

Before starting the study and 15 days after the end of the first month and the end of the second month after birth

Method of measurement

Dennis self-efficacy questionnaire, exclusive feeding checklist, baby weighing scale

Secondary outcomes

1

Description

Self-efficacy is the mother's perceived ability to breastfeed her baby

Timepoint

Before starting the intervention, then on the 15th day, the end of the first month and the end of the second month of birth

Method of measurement

1- Weighing the baby using a scale 2- The Fax and Dennis breastfeeding self-efficacy questionnaire includes 33 questions with a positive weight based on the Likert scale 3- The exclusive feeding check list

Intervention groups

1

Description

Intervention group: The intervention group will be randomly assigned to the face-to-face training group in the form of 3 weekly sessions in weeks 35-37 and one session in 3-5 days after delivery, educational information according to the content of the group. The application will be provided (all trainings are based on the training courses of the Ministry of Health)

Category

Behavior

2

Description

Intervention group: Intervention groups: The second intervention group will be randomly assigned an educational application (created by the project partner) will be installed on their mobile phone, so that how to use and access information is fully taught to mothers in a 15-30 minute session. Then they will be given explanations on how to use the application.

Category

Behavior

3

Description

Control group: Control group: The control group will be placed in this group after randomly allocating the samples and will only receive the routine care and training of the health center.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rezashahr comprehensive health service center
Community Verified icon

Full name of responsible person

fateme erfania

Street address

8 Zakaria, 11 Pirouzi, Pirouzi Blvd. Mashhad,

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2

Recruitment center

Name of recruitment center

Sarafrazan comprehensive health service center
Community Verified icon

Full name of responsible person

fateme erfania

Street address

, Pirouzi 26, Farqani 7, next to Bostan Rose, Mashhad

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Recruitment center

Name of recruitment center

Comprehensive Ab and Bargh health service center

Full name of responsible person

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Email

erfaniaF@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatema erfanian

Street address

Iran, Mashhad, Razavi Khorasan Province, University
St., Central Organization of Mashhad University of
Medical Sciences, Qureshi Building Community
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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

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

fateme baluch

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

fateme erfanian

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Undecided - It is not yet known if there will be 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