# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**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**

Self-efficacy, baby weighing, amount of exclusive feeding

## 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)

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**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

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Mashhad

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Razavi Khorasan

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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-efficac

**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 erfanian

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**2**

**Recruitment center**

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**3**

**Recruitment center**

**Name of recruitment center**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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