

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### The effect of online health literacy-based education on the self-efficacy of primiparous breast feeding women

#### Protocol summary

##### Study aim

To determine the effect of health literacy education on breastfeeding self-efficacy in primiparous women.

##### Design

A clinical trial with a control group and an intervention group with an open label and randomized design is conducted on 80 postpartum women. RANDBETWEEN command of Excel software was used for randomization.

##### Settings and conduct

Sampling will be done in the health centers of Chalus city. In the intervention group, 4 training sessions will be conducted in the Sky Room. The control group will receive the standard care routine post partum

##### Participants/Inclusion and exclusion criteria

Having a smart mobile phone- The ability to use smart phones- Primipara- Healthy fetus- Single fetus- Full term baby- Mothers who feed their babies by themselves- Consent to participate in the study

##### Intervention groups

Intervention group: 4 sessions of 45-60 minutes (one session per week) will receive interventions as a group of 40 people in the Sky Room. The interventions will be implemented by a master's degree student in counseling in midwifery. Mother, disadvantages, benefits of breast milk and colostrum, correct breastfeeding status, methods of continuing breastfeeding, danger signs for mother and newborn. The control group will receive: standard care. After the end of the intervention, they will receive an educational file

##### Main outcome variables

The primary outcome: Breastfeeding self-efficacy  
Secondary outcome: level of breastfeeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150608022609N10**

Registration date: **2023-02-07, 1401/11/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-07, 1401/11/18**

Update count: **0**

##### Registration date

2023-02-07, 1401/11/18

##### Registrant information

###### Name

Zohre Shahhosseini

###### Name of organization / entity

Mazandaran University of Medical Science, Nasibe  
School Of Nursing and Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 7342

###### Email address

z.shahhosseini@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-05-21, 1402/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of online health literacy-based education on the self-efficacy of primiparous breast feeding women

##### Public title

The effect of online health literacy-based education on the self-efficacy of primiparous breast feeding women

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having a smart phone Ability to use a smart phone  
Primipara healthy fetus Single fetus Full term baby  
Mothers who feed their babies by themselves Consent to participate in the study  
**Exclusion criteria:**  
Under the treatment of psychiatric diseases with a doctor's diagnosis Hospitalization of mother or baby  
Inability to breastfeed due to breast problems Death of mother or baby

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After completing the sample volume, it will be used for random allocation using the block sampling method, the unit of each block is based on the individual. The samples will be assigned to two groups (intervention and control) using block classification. Blocking process using Excel software will be placed in 18 quadruple blocks (the total sample size is 80 people). In this way, the numbers will be generated randomly with the RANDBETWEEN command in the range of 1 to 6. Then, according to the production values of one of the blocks (for the production number of 1 CTTC block, for the production number of 2 CTCT blocks and so on) the samples will be selected and allocated. Based on this, in the Excel software, between the number one and six, if the number 2 (CTCT block) is randomly selected, the first person enters the intervention group, the second person enters the control group, the third person enters the intervention group and the fourth person enters 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

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Square

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816715793

##### Approval date

2022-12-04, 1401/09/13

##### Ethics committee reference number

IR.MAZUMS..REC.1401.15016

## Health conditions studied

### 1

#### Description of health condition studied

Singleton pregnancy

#### ICD-10 code

XV

#### ICD-10 code description

Pregnancy, childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Breastfeeding self-efficacy

#### Timepoint

Before the intervention and immediately and three weeks and six weeks after the intervention

#### Method of measurement

Breastfeeding self-efficacy questionnaire

## Secondary outcomes

### 1

#### Description

Lactation level

#### Timepoint

Before the intervention and immediately and three weeks and six weeks after the end of the intervention

#### Method of measurement

Labbok breastfeeding level checklist

### 2

#### Description

Satisfaction with the intervention

#### Timepoint

Immediately and three weeks and six weeks after the end of the intervention

## Method of measurement

Visual Analog Scale: Satisfaction

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: In the intervention group, there are 4 sessions of 45-60 minutes (one session per week) interventions (including training and advice on personal health and the benefits of breastfeeding, comparing the advantages and disadvantages of breast milk and formula, breast changes during breastfeeding and identifying and treating signs of maternal risk After delivery and training to identify and treat infant danger signs and signs of breast milk sufficiency for the baby, as well as mothers' false beliefs about breastfeeding and methods of continuing breastfeeding, milking and storing breast milk and dimensions of health literacy including obtain information/understand information/appraise information/use information) will receive in groups of 20 people in Sky Room.

#### Category

Behavior

### 2

#### Description

Control group: Will receive routine care.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health care center of Chalus city number 1

##### Full name of responsible person

Mahshid Rezayi

##### Street address

Health Center No. 1, Shahid Harajpoor Street, Palujdeh, Chalus

##### City

Chalus

##### Province

Mazandaran

##### Postal code

4651146184

##### Phone

+98 11 5222 0260

##### Email

neginkalvaninytali@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Health care center of Chalus city number 3

## Full name of responsible person

Mahshid Rezayi

## Street address

Imam Reza Blvd., Alavikla, Chalus

## City

Chalus

## Province

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### 3

#### Recruitment center

##### Name of recruitment center

Health care center of Chalus city number 2

##### Full name of responsible person

Mahshid Rezayi

##### Street address

In front of Mazar, Ashura Street, Bazarroz, Chalos

##### City

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Ebrahimnejad

##### Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Avenue

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+98 11 3325 7230

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sexualhealthresearchcenter@gmail.com

#### Grant name

#### Grant code / Reference number

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

No  
**Title of funding source**  
Mazandaran 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**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Negin Kalvani  
**Position**  
Masters student  
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Bachelor  
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Midwifery  
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## Person responsible for scientific inquiries

### Contact

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PhD in Reproductive Health  
**Latest degree**  
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## Person responsible for updating data

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Bachelor  
**Other areas of specialty/work**  
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neginkalvaninytali@gmail.com

## 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