

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

Mazandaran

Postal code

4651146184

Phone

+98 11 5225 2920

Email

neginkalvaninytali@gmail.com

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

Chalus

Province

Mazandaran

Postal code

4651146184

Phone

+98 11 5228 2162

Email

neginkalvani@gmail.com

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

City

Sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3325 7230

Email

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
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Shirazi Avenue
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 5232 8518
Email
neginkalvaninytali@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Zohreh Shahhosseini
Position
PhD in Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Shirazi Avenue
City

sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3337 4750
Email
zshahhosseini@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Negin Kalvani
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Nasibeh Nursin and Midwifery Faculty, Vesal Shirazi Avenue
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3337 4750
Email
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