

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Compare effectiveness of the Distance Education Program and Routine training on the Mothers' Empowerment in Breast-Feeding

#### Protocol summary

##### Study aim

Determining the Effectiveness of a Distance Education Program on Mothers' Empowering in Breastfeeding

##### Design

72 pregnant women referred to midwifery clinics of educational hospitals affiliated to Babol University of Medical Sciences will be eligible for inclusion in the study (available sampling method) and then Randomized in the two groups of intervention and control.

##### Settings and conduct

Midwifery clinics of educational hospitals affiliated to Babol University of Medical Sciences (Ayatollah Rouhani and Yahya Nejad Hospitals)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Informed consent, Age over 18 years, the first pregnancy, 30 to 32 weeks' gestational age, normal breast and nipple, ability to understand and complete questionnaires, lack of physical and mental disorders, Independence on any type of substance according to the mother's personal statement, the singleton pregnancy, Access to the Telegraph mobile phone Exclusion criteria: High-risk pregnancy (having a disease that interferes with breastfeeding), no cell phone and Lack of internet access.

##### Intervention groups

The intervention group, in addition to the routine training during pregnancy and after delivery, provides the educational package for lactation in accordance with the education curriculum of the Ministry of Health (the importance and benefits of breastfeeding for mother and infant, proper lactation techniques, How to feed and store milk, possible lactation problems and artificial feeding risks, how to deal with breast problems and lactation) will be sent by telegram message from week 32 every week (on a specified day) to six weeks. The control group will receive only routine education during pregnancy and postpartum

##### Main outcome variables

Mothers' breastfeeding Empowerment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180520039728N1**

Registration date: **2018-07-03, 1397/04/12**

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

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

##### Registration date

2018-07-03, 1397/04/12

##### Registrant information

##### Name

Fatemeh Bakouei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 5313

##### Email address

f.bakouei@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Compare effectiveness of the Distance Education Program and Routine training on the Mothers' Empowerment in Breast-Feeding

#### Public title

Effectiveness of the Distance Education Program on the Mothers' Empowerment in Breast-Feeding

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Informed consent Age over 18 years The first pregnancy 30 to 32 weeks' gestational age Having normal breast and nipple Ability to understand and complete questionnaires, lack of physical and mental disorders, Independence on any type of substance according to the mother's personal statement The singleton pregnancy Access to the Telegraph mobile phone

##### Exclusion criteria:

High-risk pregnancy ( Having a disease that interferes with breastfeeding) No cell phone Lack of internet access

#### Age

From **18 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **72**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random number table will be used to allocate random persons to groups. A set of non-template numbers or a system that has been created entirely randomly and in the form of a table.

#### 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 Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganj Afroz Ave, Babol

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Approval date

2018-05-12, 1397/02/22

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.031

## Health conditions studied

### 1

#### Description of health condition studied

Breastfeeding Empowerment

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The Mothers' Empowerment in Breastfeeding

#### Timepoint

Before intervention, 4 and 8 weeks after childbirth

#### Method of measurement

The breastfeeding empowerment questionnaire

## Secondary outcomes

### 1

#### Description

Duration of exclusive breastfeeding after childbirth

#### Timepoint

4 and 8 weeks after childbirth

#### Method of measurement

Follow-up questionnaire on fertility variables

## Intervention groups

### 1

#### Description

Intervention group: The lactation training package provided In accordance with the training curriculum Ministry of Health of the country will Send Via a telegram message from week 32 of gestation weekly up to 6 weeks, follow up to revive of lactation training package via message at Intervention group.

#### Category

Behavior

### 2

#### Description

Control group: Only the routine pregnancy and postpartum education Will be taken (Face-to-face

training provided by health care workers during maternity care and training provided by postpartum health care staff to client, face-to-face).

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Rohani hospital

**Full name of responsible person**

Fatemeh Bakouei

**Street address**

Ayatollah Rohani hospital, Ganj Afroz Ave, Babol

**City**

Babol

**Province**

Mazandaran

**Postal code**

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**Phone**

+98 11 3219 5313

**Email**

bakouei2004@yahoo.com

**2****Recruitment center****Name of recruitment center**

Shahid Yahyanajad hospital

**Full name of responsible person**

Fatemeh Bakouei

**Street address**

Shahid Yahyanajad hospital, Modarres Ave, Babol

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Reza Ghadimi

**Street address**

Babol University of Medical Sciences, ganj Afroz Ave,

Babol

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**Phone**

+98 11 3219 9592

**Email**

rezaghadimi@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh bakouei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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

Babol University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh bakouei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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