

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Investigating the effect of breastfeeding education mobile software on Mothers satisfaction

#### Protocol summary

##### Study aim

Investigating the effect of using breastfeeding education mobile software on mothers' satisfaction

##### Design

384 / 5,000 Translation results In the intervention group, clients and their caregivers, in addition to receiving educational materials and participating in childbirth and breastfeeding preparation classes of Ayatollah Taleghani Center, will be trained using the consolidated discharge method, (education as usual and with application), the patients of the control group will receive necessary training and participate in childbirth and breastfeeding preparation classes of Ayatollah Taleghani Center and will be discharged from the hospital.

##### Settings and conduct

The present research will be carried out experimentally and by randomized clinical trial method in Ayatollah Taleghani Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the research: The mother's ability to breastfeed the baby, being literate, having access to a mobile phone with the ability to download software

##### Intervention groups

In the intervention group, clients and their caregivers, in addition to receiving educational materials and participating in childbirth and breastfeeding preparation classes of Ayatollah Taleghani Center, will be trained using the combined discharge method (education as usual and with application) in the department.

##### Main outcome variables

Weighing the baby in the first 6 months of birth, promoting breastfeeding of mothers

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210131050189N2**

Registration date: **2023-03-14, 1401/12/23**

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

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

##### Registration date

2023-03-14, 1401/12/23

##### Registrant information

###### Name

Raziyeh Ghafouri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3335 4520

###### Email address

ghafouri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-11, 1401/09/20

##### Expected recruitment end date

2023-09-11, 1402/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of breastfeeding education mobile software on Mothers satisfaction

##### Public title

Investigating the effect of breastfeeding education mobile software on Mothers satisfaction

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Being literate Mobile access with the ability to download software Baby's ability to breastfeed

### Exclusion criteria:

Inability of mother and baby to breastfeed for any reason, such as illness of mother or baby

## Age

From **18 years** old to **55 years** old

## Gender

Female

## Phase

0

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Before the start of the intervention, 40 white and 40 black cards are prepared and for randomization, all the cards are placed in an envelope, then the cards are drawn randomly and numbers from 1 to 80 are drawn in order. is placed Then each card is placed in a sealed envelope and its number is written on the card, and when each patient enters the study, a special envelope will be opened for him from 1 to 80 and assigned to the intervention and 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

Vice President of Research and Technology Shahid Beheshti University of Medical Sciences (Research E

##### Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

## Approval date

2022-11-13, 1401/08/22

## Ethics committee reference number

IR.SBMU.RETECH.REC.1401.550

## Health conditions studied

### 1

#### Description of health condition studied

Promotion of breastfeeding

#### ICD-10 code

R63.3

#### ICD-10 code description

Feeding difficulties

## Primary outcomes

### 1

#### Description

Weighing the baby in the first 1 to 6 months of birth

#### Timepoint

6 month

#### Method of measurement

Measuring the baby's weight monthly

### 2

#### Description

ارتقا شیر دهی مادران

#### Timepoint

monthly

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Clients and their caregivers, in addition to receiving educational materials and participating in childbirth and breastfeeding preparation classes of Ayatollah Taleghani Center, will be trained using the consolidated discharge method, (education as usual and with application). Training using mobile phones will be such that all educational content is designed in a mobile application and provided to the participants through an internet link and installed on the participants' mobile phones.

#### Category

N/A

### 2

#### Description

Control group: Clients and their caregivers receive educational materials in the form of paper pamphlets

and participate in the childbirth and breastfeeding training class of Ayatollah Taleghani Center.

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ayatollah Taleghani Center,

**Full name of responsible person**

Raziyeh Ghafouri

**Street address**

7th Floor, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

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**Province**

Tehran

**Postal code**

19839-63113

**Phone**

+98 21 2303 1100

**Email**

taleghani@sbmu.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

shahid beheshti university of medical science

**Street address**

Iran, Tehran Velenjak St. , Shahid Chamran Highway

**City**

tehran

**Province**

Tehran

**Postal code**

19839-63113

**Phone**

+98 21 2243 9770

**Email**

Intl\_office@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raziyeh Ghafouri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Iran, Tehran Velenjak St. , Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2243 9982

**Email**

raziieghafouri@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Raziyeh Ghafouri

**Position**

Assistant Professor

**Latest degree**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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+98 21 2243 9982

**Email**

raziehghafouri@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

By request from the coresponder author via email

**When the data will become available and for how long**

after data gathering

**To whom data/document is available**

academic researcher

**Under which criteria data/document could be used**

By request from the coresponder author via email

**From where data/document is obtainable**

By request from the coresponder author via email

**What processes are involved for a request to access data/document**

By request from the coresponder author via email

**Comments**