

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### **Effectiveness of a smartphone based, educational intervention on breastfeeding self-efficacy and mothers' health literacy with infants in their first six month of life in Urmia, Iran.**

#### **Protocol summary**

##### **Study aim**

Assessing the impact of an educational intervention based on a smartphone application for improving maternal breastfeeding of infants in their first six months of life in Urmia, Iran.

##### **Design**

A Randomized control trial study was conducted with 40 new mothers of their first child with less than three months of age assigned to each intervention (mobile app education) and control group (usual care). Randomization was conducted using a web-based randomization tool.

##### **Settings and conduct**

The study was conducted in a health center in Urmia, Iran. Data collectors and care providers were blinded to group assignment. The researcher preparing the randomization procedure was blind to participants and had not any cooperation in the recruitment process. For avoiding the study bias it was required that the control and intervention group mothers have no access to each other.

##### **Participants/Inclusion and exclusion criteria**

Based on inclusion criteria new mothers experiencing their firstborn child with less than three months of age were selected. Subjects are excluded in conditions that if they did not have a smartphone or have a medical disorder requiring treatment.

##### **Intervention groups**

In the intervention arm, mothers have distributed a mobile application which was for educating them about the required knowledge for breastfeeding. In the control arm, mother and child pairs received routine health service treatments only.

##### **Main outcome variables**

This study results with the aim to assess the effect of a smartphone-based maternal education on breastfeeding among primiparous mothers in the relational areas of the

mother knowledge, attitude, practice, and self-efficacy on breastfeeding infants, showed higher improved scores for intervention group mothers in front of the control group.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20190705044103N2**

Registration date: **2020-09-25, 1399/07/04**

Registration timing: **retrospective**

Last update: **2020-09-25, 1399/07/04**

Update count: **0**

##### **Registration date**

2020-09-25, 1399/07/04

##### **Registrant information**

##### **Name**

Navisa Seyyedi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 44 3345 0459

##### **Email address**

ns.seyyedi@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2019-01-21, 1397/11/01

##### **Expected recruitment end date**

2019-05-10, 1398/02/20

##### **Actual recruitment start date**

2019-01-21, 1397/11/01  
**Actual recruitment end date**  
2019-06-25, 1398/04/04  
**Trial completion date**  
2019-12-11, 1398/09/20

**Scientific title**  
Effectiveness of a smartphone based, educational intervention on breastfeeding self-efficacy and mothers' health literacy with infants in their first six month of life in Urmia, Iran.

**Public title**  
An educational intervention based on a mobile phone application for improving maternal breastfeeding of infants in their first six month of life in Urmia, Iran.

**Purpose**  
Education/Guidance  
**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
New mothers experiencing their firstborn child Infants with less than three month of age  
**Exclusion criteria:**  
If they were not in possession of a smart phone Having a medical disorder requiring treatment

**Age**  
From **18 years** old to **38 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **80**  
Actual sample size reached: **80**

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

**Randomization description**  
Random Allocation Software 1.0 (<https://random-allocation.software.software.informer.com/1.0/>) was utilized to allocate the mother and child pair to intervention or control groups in a 1:1 ratio. The permuted block method of randomization for a block size of four was used. Based on the limited size of the trial, this procedure was preferred to simple randomization in order to maintain an adequate balance in the number of participants allocated to each of the study groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
For avoiding the bias in this study, the control and intervention group were not accessible to each other. So the participants were recruited separately in an isolated room. Data collectors and care providers were blinded to group assignment and they just investigated the inclusion criteria in the defined clinic. The randomization was performed by a researcher with no access to

participant information and who did not participate in the enrollment process.

**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Urmia University of Medical Science  
**Street address**  
Urmia University of Medical Sciences, Nazloo Campus, Sero Road  
**City**  
Urmia  
**Province**  
West Azarbaijan  
**Postal code**  
571478334

**Approval date**  
2017-06-07, 1396/03/17

**Ethics committee reference number**  
IR.UMSU.REC.1396.105

**Health conditions studied**

1

**Description of health condition studied**  
Child growth and development

**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

1

**Description**  
Maternal breastfeeding self-efficacy  
**Timepoint**  
Before intervention and three months after intervention  
**Method of measurement**  
Questionnaire

2

**Description**  
KAP (Knowledge, Attitude, Practice)  
**Timepoint**  
Before intervention and three months after intervention  
**Method of measurement**  
Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Android compatible application was developed then tested and trialed through one week with cooperating test group consists of technical experts and some usual users. The designed application is for educating mothers about the required knowledge for breastfeeding. In accordance with the Ministry of Health and Maternity Guidelines for maternal and child health in the form of a comprehensive integrated healthy child care guide have been compiled in a list of things to be taught to mothers and used in the form of an educational content in the application. In the intervention arm, mothers were distributed this application installed on their phones which was featured by a topic-oriented educational manner to facilitate discovering the solution of encountered problems through lactating process. The intervention generally was scheduled for 3 month period. The mothers were followed-up and encouraged in using the app by calling them during the intervention.

#### Category

Behavior

### 2

#### Description

Control group: In the control group, mother and child pairs were visited in the health center by a routine health service. The babies were vaccinated and assessed on developmental aspects based on weight, height and screening tests to determine the child abilities.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sarallah Well-child clinic

##### Full name of responsible person

Navisa Seyyedi

##### Street address

Nazloo Campus, Sero Road

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

571478334

##### Phone

+98 44 3345 0459

##### Email

ns.seyyedi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Iraj Mohebbi

##### Street address

Nazloo campus, Sero road

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

7515117175

##### Phone

+98 44 7557 5733

##### Email

mohebbi\_iraj@yahoo.co.uk

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Bahlol Rahimi

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Informatics

##### Street address

Nazloo Campus, Sero Road

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

571478334

##### Phone

+98 44 3345 0459

**Email**

bahlol.rahimi@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Bahlol Rahimi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Informatics

**Street address**

Nazloo Campus, Sero Road

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

571478334

**Phone**

+98 44 3345 0459

**Email**

bahlol.rahimi@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Bahlol Rahimi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Informatics

**Street address**

Nazloo Campus, Sero Road

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

571478334

**Phone**

+98 44 3345 0459

**Email**

bahlol.rahimi@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**

Results will be presented in an article to be published in a leading scientific journal during 2021

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

Intention to publish date 1/1/2021

**To whom data/document is available**

All researchers

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

Results will be presented in an article to be published in a leading scientific journal during 2021 so after publishing the data could be used

**From where data/document is obtainable**

Results will be presented in an article to be published in a leading scientific journal during 2021 and the applicant could use the researchers email to communicate bahlol.rahimi@gmail.com

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

Results will be presented in an article to be published in a leading scientific journal during 2021 and the applicant could use the researchers email to communicate bahlol.rahimi@gmail.com

**Comments**