

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparative effect of peer-based education using mobile phone and face-to-face education on fear of childbirth in primigravida women in comprehensive health centers

#### Protocol summary

##### Study aim

Comparison of the effect of peer education based on mobile phone use and face to face training on fear of childbirth in the first pregnant women referred to Meshginshahr comprehensive health centers

##### Design

Experimental trial with three groups, control group, face-to-face training and mobile phone training by peers on the first 60 pregnant women 24-34 weeks, SPSS 16 software is used to evaluate the results.

##### Settings and conduct

First pregnant women 24-34 weeks referring to comprehensive health centers who have obtained a score of 80-100 in the fear of childbirth in the questionnaire of fear of childbirth are included in the study. Individuals are divided into three groups: one control group and two intervention groups 1 and 2. The results will be evaluated immediately after the intervention and one month later. The control group receives only routine care.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Literacy of Persian, age range 18 to 35 years Being pregnant first, Gestational age 24 to 32 weeks No stressful events in the last 6 months Lack of medical indication for cesarean section No underlying mental illness Having a mobile phone, internet connection, ability to use WhatsApp application. Earn a score of 85 and above on the Fear of Childbirth Questionnaire Exclusion criteria Increased disease in pregnancy Any complication in pregnancy such as high blood pressure during pregnancy, premature rupture of the bladder, premature birth Lack of contact information Mental illness

##### Intervention groups

Intervention group 1 receives six 90-minute face-to-face training sessions in health centers Intervention group 2 receives six 90-minute training sessions through

WhatsApp The control group receiving routine pregnancy care

##### Main outcome variables

Fear of childbirth Pregnancy anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200404046943N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **retrospective**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

##### Registration date

2020-09-09, 1399/06/19

##### Registrant information

##### Name

Fereshta Rostame

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3252 8948

##### Email address

za.sa.rostame@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative effect of peer-based education using mobile phone and face-to-face education on fear of childbirth in primigravida women in comprehensive health centers

**Public title**  
Comparison of face-to-face training and mobile phone training on fear of childbirth

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Reading and writing Persian literacy Age range 18 to 35 years Singleton primigravida women Pregnancy age 24 to 32 weeks No history of infertility Lack of stressful events in the last 6 months Lack of medical indications for cesarean section Lack of mental illness Having a mobile phone with Android operating system, the ability to connect to the Internet, the ability to use WhatsApp Get a score of 85 or higher on the Vijma Questionnaire

**Exclusion criteria:**  
Any disease added to the pregnancy that requires a cesarean section for the mother Having any complications during pregnancy such as high blood pressure during pregnancy, decompression, fetal death, premature rupture of the bladder, preterm delivery Mental illness No contact information

**Age**  
From **18 years** old to **35 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **66**

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

**Randomization description**  
In the study groups, Random allocation will be made with blocking methods. First, all possible combinations of AABCC blocks will be listed, one code will assign to each of them, and then 11 codes will be select randomly. They will be Blind to ensure that there is no bias. After selecting them, go to the blocks corresponding to each code, and then according to the available combinations, people will enter the study groups.

**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 Urmia University of Medical Sciences

##### Street address

Khayyam Street

##### City

Meshginshahr

##### Province

Ardabil

##### Postal code

5661844518

#### Approval date

2020-03-17, 1398/12/27

#### Ethics committee reference number

IR.UMSU.REC.1399.018

## Health conditions studied

### 1

#### Description of health condition studied

Fear of childbirth

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Childbirth Fear Score in the Vijma Birth Fear Questionnaire

#### Timepoint

Pre-test (before the start of the intervention), post-test (immediately after the intervention), follow-up (one month after the intervention)

#### Method of measurement

General score obtained from the Vijma A Fear of Childbirth Questionnaire

### 2

#### Description

Pregnancy Anxiety Score in Shortened Questionnaire Pregnancy Anxiety Wendenberg

#### Timepoint

Pre-test (before the start of the intervention), post-test (immediately after the intervention), follow-up (one month after the intervention)

#### Method of measurement

The total score obtained from the abbreviated questionnaire of Wendenberg

## Secondary outcomes

### 1

#### Description

Fear of childbirth

#### Timepoint

Follow-up test (one month after the last intervention session)

#### Method of measurement

The overall score obtained from the Vija Birth Fear Questionnaire

### 2

#### Description

Pregnancy Anxiety

#### Timepoint

Follow-up test (one month after the last intervention session)

#### Method of measurement

The overall score obtained in the shortened Wondenberg Pregnancy Anxiety Questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: Face to face training: 6 training sessions held once a week, and the time of face-to-face training will be 90 minutes. The first sessions Content is Introducing peers and getting acquainted with each other, educating clients about the reproductive system and reproduction of women and the names and functions of some organs involved in childbirth, common complaints during pregnancy, and how to deal with them. Stretching exercises, summarizing the first session and Assignment, and get feedback (feedback on mobile education will be self-reported by mothers). The second session's content is a group discussion on anxiety and stress-related to pregnancy and ways to deal with it, including relaxation methods and breathing techniques, the importance of prenatal care, danger symptoms, personal health, final summary, and assigning feedback. The third session's content is a Review of homework, and a brief review of the previous session, self-control of emotions, nutrition and maintenance of a proper diet, childbirth and pain relief methods, gaining the support of a spouse or a loved one, final summary, Assignment, and provide feedback. The fourth session's content is a Review of homework and a brief review of the previous session, training to introduce common mental errors in childbirth, the importance of vaginal delivery, final summary, homework assignment, and feedback. The fifth sessions Content is a Review of homework and a brief review of the previous session, description of labor stages, labor and delivery process, familiarity with hospital routine, application of distracting behavioral techniques, deep breathing, muscle relaxation, expression of peer experiences of labor and labor stages, summary, Assignment and provides feedback. The sixth

session's content is a review of homework and a brief review of the previous session. It teaches people how to use methods to reduce pain and stretch and to breathing exercises to people, teaching breastfeeding, and caring for the baby.

#### Category

Other

### 2

#### Description

Intervention group2: Intervention group via mobile phone Educational content in WhatsApp program in 4 groups of 6-5 people through group chat, sending an audio file and educational video by peers to mothers and questions and answers with group members and discussing training presentations Based on the experience of delivery, the counterparts will be presented. The sessions will be weekly for 90 minutes.

#### Category

Other

### 3

#### Description

Control group.The routine care will receive to the control group during pregnancy, and no intervention will accrue.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Meshginshahr city health center

##### Full name of responsible person

Hossein Sharifi

##### Street address

Azadi Square

##### City

Meshginshahr

##### Province

Ardabil

##### Postal code

5661967595

##### Phone

+98 45 3252 4515

##### Email

Meshghinhc@arums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Iraj Mohebbi

##### Street address

Urmia University of Medical Sciences,Resalat  
Boulevard,Urmia City,West Azerbaijan Province,Iran

**City**

Orumieh

**Province**

West Azarbaijan

**Postal code**

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**Phone**

+98 44 3193 7224

**Fax**

+98 44 3224 0642

**Email**

lrajmohebbi@umsu.ac.ir

**Web page address****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**

Fereshteh Rostami

**Position**

Master's degree student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

The first floor of Sadra building, sub-street 1,  
Khayyam street, Meshginshahr city, Ardabil province,  
Iran

**City**

Meshginshahr

**Province**

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**Postal code**

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**Phone**

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**Email**

Za.sa.rostame@gmail.com

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Roqia Bayrami

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

School of Nursing and Midwifery, Nazloo  
Campus,Urmia University of Medical  
Sciences,UrmiaWest Azerbaijan Province,Iran

**City**

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**Province**

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rozabayrami@yahoo.com

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Fereshteh Rostami

**Position**

Master's degree student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Email**

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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**

Not applicable

**Data Dictionary**

Not applicable