Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative effect of peer-based education using mobile phone and face-to-face education on fear of childbirth in primigravia 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 primigravia 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 primigravia 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 AABBCC 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 Vijma 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
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Province
Ardabil
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Phone
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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

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Province
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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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Full name of responsible person
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Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Province
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Person responsible for updating data

Contact

Name of organization / entity
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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
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Province
Ardabil

Postal code
5661844518

Phone
+98 45 3252 8948

Email
Za.sa.rostame@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
Not applicable

Data Dictionary
Not applicable