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
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 AABBC 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 session's 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 group 2: 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
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
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Ardabil
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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
Street address
The first floor of Sadra building, sub-street 1, Khayyam street, Meshginshahr city, Ardabil province, Iran
City
Meshginshahr
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