

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Survey the effect of educational intervention using mobile application on fear of childbirth in pregnant women

Protocol summary

Study aim

Determining the effect of educational intervention using mobile application on fear of childbirth in pregnant women referring to the Alzahra education, research & remedial center in Rasht city in 2020

Design

A quasi-experimental study has two groups of intervention and control, non blinded and 57 people in each group.

Settings and conduct

The place of the study is the Prenatal Care Clinic of Alzahra education, research & remedial center in Rasht city. The test group will receive training based on mobile software. The questionnaires are completed 3 times, 2 times during pregnancy, and 1 time immediately after delivery.

Participants/Inclusion and exclusion criteria

Entry criteria: nulliparity; gestational age 28-32 weeks; single pregnancy; reading and writing literacy; Iranian citizenship; interest in participating in the study; having a mobile phone with Android system and the ability to install software; ability to use and work with mobile software; no underlying and chronic disease; lack of indication for cesarean section; decided to have a leading delivery at Alzahra education, research & remedial center; no history of participating in prenatal care training programs and childbirth preparation classes; no education in medical fields. Exit criteria: reluctance to continue participating in the study; occurrence of labor at any stage of educational intervention.

Intervention groups

This study includes two groups of control and intervention. The control group did not receive any intervention from the researcher. The test group will receive training based on mobile software. Questionnaires are completed in 3 rounds in both test and control groups, 2 times during pregnancy (before and after the training program), and 1 time immediately

after delivery.

Main outcome variables

Fear of natural childbirth in pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210220050418N1**

Registration date: **2021-03-13, 1399/12/23**

Registration timing: **prospective**

Last update: **2021-03-13, 1399/12/23**

Update count: **0**

Registration date

2021-03-13, 1399/12/23

Registrant information

Name

Sara Shirzad Chenari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

sarashirzad712@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-27, 1400/01/07

Expected recruitment end date

2021-05-28, 1400/03/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Survey the effect of educational intervention using mobile application on fear of childbirth in pregnant women

Public title
Survey the effect of educational intervention using mobile application on fear of childbirth in pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Nulliparity Gestational age 28-32 weeks Single pregnancy Reading and writing literacy Iranian citizenship Satisfaction and interest in participating in the study Having a mobile phone with Android system and the ability to install software Ability to use and work with mobile software Decided to have a leading delivery at Alzahra education, research & remedial center
Exclusion criteria:
Having an underlying and chronic disease Having indications for cesarean section History of participating in prenatal care training programs and childbirth preparation classes Having education in medical fields Reluctance to continue participating in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is a quasi-experimental intervention. In order to assign individuals in the intervention and control groups, one day clients are assigned to the experimental group and the next day clients are assigned to the control group. In other words, the members of the experimental group are selected from the eligible clients on even days of the week, and the members of the control group are selected from the eligible clients on the odd days of the week.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Guilan University of Medical Sciences

Street address

In front of 17 Shahrivar Hospital, Shahid Siadati Ave. , Namjoo St.

City

Rasht

Province

Guilan

Postal code

4146939114

Approval date

2020-09-16, 1399/06/26

Ethics committee reference number

IR.GUMS.REC.1399.293

Health conditions studied

1

Description of health condition studied

Fear of childbirth in pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fear of childbirth in pregnant women

Timepoint

Before intervention, after intervention (after 8 weeks of educational intervention), immediately after delivery

Method of measurement

Will be measured by standard tool Wijma Delivery Expectancy/Experience Questionnaire. There are 2 versions of this questionnaire. Version A measures the fear of childbirth during pregnancy and version B measures the experience of mothers after childbirth. In this study, the researcher uses both versions A and B of this questionnaire. In this study, the researcher uses both versions A and B of this questionnaire. Both versions of this tool contain 33 items that are scored in a 6-point range. Scores in each question range from zero to five. The minimum score is zero and the maximum score is 165. A higher score indicates more fear. This questionnaire was first designed in Sweden by Wijma et al. (1990) and localized in Iran by Mortazavi (2017).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before the implementation of the training program, version A of the Wijma Delivery Expectancy/Experience Questionnaire in both intervention and control groups will be completed by the research units and then the training software will be installed on the test group mobile phones and these people receive this training in addition to receiving routine prenatal care. It should be noted that the control group does not receive any intervention from the researcher and will only be under routine care during pregnancy. In order not to disrupt the research process, the control group will not be informed of the installation of software on the phone of the experimental group, and this is possible by selecting the members of the experimental and control groups on separate days and not colliding with each other. The use of software during the study period will be reminded once a week by sending a text message to the mothers of the experimental group by the researcher. In order to answer the mothers in case of problems or ambiguity and questions, the researcher's phone number will be provided to the mothers. At the end of the 8-week training period, at the first visit of the research units to the hospital for care (referral time will be planned by the researcher and coordinated with individuals), again, version A of the Wijma Delivery Expectancy/Experience Questionnaire will be provided to the research units of both test and control groups and will be completed by them in the presence of the researcher. The mothers of the test and control groups will be instructed to inform the researcher of the time of their delivery (whether normal delivery or cesarean section). Version B of Wijma Delivery Expectancy/Experience Questionnaire will be provided to the study units after delivery by the researcher in person at the hospital where the delivery was completed. In this research, educational content including designing and compiling educational software by an experienced programming expert based on the explanation of the delivery process, methods of reducing labor pain, training different positions during labor and childbirth, stretching exercises, respiratory pattern, relaxation and massage. The educational content provided in the software will be taken from the book "Pregnancy and childbirth training" published by the Ministry of Health and Medical Education. This book includes 5 sections: pregnancy, childbirth, postpartum, baby care and stretching exercises, breathing pattern, relaxation and massage. The content will be extracted from the second part (childbirth) and the fifth part (stretching exercises, breathing pattern, relaxation and massage).

Category

Other

2

Description

Control group: The control group does not receive any intervention from the researcher and will only be under routine care during pregnancy. In order not to disrupt the research process, the control group will not be informed of the installation of software on the phone of the experimental group, and this is possible by selecting the members of the experimental and control groups on separate days and not colliding with each other.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra education, research & remedial Center in Rasht city

Full name of responsible person

Zahra Bostani Khalesi

Street address

In front of Azodi Stadium, Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3336 9324

Email

sarashirzad712@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

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In front of 17 Shahrivar Hospital, Shahid Siadati Ave., Namjoo St.

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z_bostani@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Shahid Beheshti Faculty of Nursing and Midwifery,
Student Park, Yakhsazi Square, Rasht

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

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Email

z_bostani@yahoo.com

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

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

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

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

Associate Professor

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Email

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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

Main and general data

When the data will become available and for how long

1 year

To whom data/document is available

Faculty Members of Shahid Beheshti Faculty of Midwifery
and Nursing, Rasht

Under which criteria data/document could be used

In order to verify the accuracy of the information and

with a written and approved request from the research deputy of Shahid Beheshti Faculty of Nursing and Midwifery, Rasht

From where data/document is obtainable

Library of Shahid Beheshti Faculty of Midwifery and Nursing of Rasht as well as a written request from the project implementer

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

Permission from the librarian of Shahid Beheshti Faculty of Midwifery and Nursing in Rasht in writing and Contact the project implementer and conduct a moral agreement

Comments