Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 13 3355 5056

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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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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Other areas of specialty/work
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Person responsible for updating data

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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