

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Investigating the Effect of Multimedia training on the Anxiety and Childbirth Experience of women with Planned Cesarean Section

Protocol summary

Study aim

Determining the effect of Multimedia training on the Anxiety and Childbirth Experience of women with planned Cesarean section

Design

A controlled, parallel-group, unblinded, randomized clinical trial on 140 pregnant women. Blocks of four will be used for random allocation.

Settings and conduct

This study is a parallel randomized clinical trial with a control group on 140 pregnant women who between the 35th and 37th week of pregnancy refer to the perinatal clinic of Akbarabadi Hospital to receive pregnancy care and are scheduled to undergo a planned cesarean delivery with anesthesia. Spinal cord will be done. For women in the test group individually, a 4-6 minute educational video including all aspects of cesarean surgery will be shown in the consultation room of the clinic on the researcher's laptop. The control group will not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian, women aged 18 to 45, ability to read and write Exclusion criteria: suspicion of congenital anomaly of the fetus, known mental disorder or history of taking anti-anxiety drugs and tranquilizers, history of infertility

Intervention groups

In the test group, a 4-6 minute individual training session will be shown on the researcher's laptop in the form of multimedia training based on educational video, including all aspects of cesarean section. Then this video is provided to the mother through messenger for unlimited viewing at home. There is no intervention for people in the control group.

Main outcome variables

Anxiety score from the Spielberger Anxiety Questionnaire ; Childbirth Experience score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N13**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Multimedia training on the Anxiety and Childbirth Experience of women with Planned Cesarean Section

Public title

The effect of educational film on pre-cesarean anxiety and childbirth experience

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Women aged 18 to 45 Ability to read and write

Exclusion criteria:

Suspicion of Congenital Anomaly of the Fetus Known Mental Disorder or History of Taking Anti-anxiety Medications and Sedatives History of Infertility

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of people in the test and control group will be done using the quadruple block method (probabilistic type) using the site <http://randomization.com/>. Blocking is such that in this study, with 140 sample people, 70 people will be allocated to each group (the test group is considered to be A and the control group is considered to be B). Two defaults are considered, the size of each block is at least twice the number of groups (4 groups in each block) and the number of repetitions of groups is equal. According to the sample size of 140 people and the size of each block is 4, finally 35 blocks will be obtained. Then, using the site <http://randomization.com/>, the order of placement of the blocks and as a result the people of the test and control group is determined using the software. In order to hide the random allocation process, the names of the groups will be placed in opaque envelopes, and these envelopes will be numbered from 1 to 140 and arranged in a box. The researcher who conducts the sampling is unaware of the contents of the envelopes. The content of the envelopes will indicate the study groups, and after entering the study and completing the informed consent form, the participants will pick the first envelope in order of number and according to the content of the envelope, they will be placed in one of the two test and control 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 Iran University of Medical Science

Street address

Next to Milad Tower, Hemet Highway, Tehran

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Province

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Postal code

1449614535

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.IUMS.REC.1401.959

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Childbirth Experience

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Anxiety score in the state section of the Spielberger Anxiety Questionnaire

Timepoint

When entering the study, 30 minutes after the intervention in the perinatal clinic of the hospital, 30 minutes after being admitted to labor on the day of the operation and the evening of the day after the cesarean section.

Method of measurement

State section of the Spielberger Anxiety Questionnaire

2

Description

Childbirth Experience Score in the Questionnaire for Assessing the Childbirth Experience

Timepoint

The evening of the day after cesarean section

Method of measurement

Short version of Questionnaire for Assessing the Childbirth Experience

Secondary outcomes

1

Description

Overall satisfaction score for cesarean delivery

Timepoint

The evening of the day after cesarean section

Method of measurement

A general question about overall satisfaction with cesarean delivery in a demographic-midwifery researcher-made questionnaire in which the mother rates her satisfaction with anesthesia and cesarean delivery from 1 to 10.

Intervention groups

1

Description

Intervention group: In this research, the content of the intervention will be prepared in the form of a 4-6 minute educational film based on the principles of Mayer's multimedia education in the form of video, animation, images in MPEG-4 (MP4) format, and after entering the study of the educational film individually It will be displayed for the mother on the researcher's laptop in the consultation room of the Perinatal Clinic of Akbarabadi Hospital. This video includes trainings for familiarizing women undergoing planned cesarean section with all aspects of cesarean section as well as preparation for the operation: definition of cesarean section and its common indications, real images with explanations of the mother's admission and hospitalization process in the hospital and staff. The Medical staff that the mother will probably face, pre-operative medical care, operating room, mother's position for spinal anesthesia, animation to explain the anatomy of spinal anesthesia, animation of surgical incision and delivery of the baby, skin-to-skin contact images of mother and baby , the recovery room after surgery and the recovery process in the hospital. This video does not contain blood images and the dangers of spinal anesthesia. The educational content of this video is based on the latest health guide and service standard "Routine midwifery care, including before delivery, cesarean delivery and post-cesarean care" (Secretariat of the Strategic Council for Compilation of Health Guides, 1400) and also based on the latest trainings of American College of Obstetricians and Gynecologists, Royal College of Obstetricians and Gynecologists and National Health

Service of England.

Category

N/A

2

Description

Control group: There is no intervention for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

Sara Sharafi

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available