Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational intervention based on the Theory of Planned Behavior on the intention and Behavior of vaginal birth after Previous cesarean among pregnant women referred to health centers in Ardabil.

Protocol summary

Study aim

Determining the effect of education based on the theory of planned behavior on the intention and behavior of natural delivery after previous cesarean section in pregnant women

Design

The study have a control and a intervention parallel randomized groups, on 70 people. By selecting the numbers, the eve number to the control and the odd number to the intervention.

Settings and conduct

study is performed on pregnant mothers with a history of cesarean section with two groups of control and intervention. The control group will receive routine care. After completing the study, a training session on educational content will be provided to them with an educational pamphlet. For the intervention group, training will be in 4 sessions. classes will be held in groups of 7 to 10 people. The education of all groups will be same and adjusted based on the pre-test analysis. content based on the theory of planned behavior.The time of training will be 90 min. It will include topics related to the benefit and disadvantages of each of delivery methods, pictures and videos related to the delivery process for training. In the last session, the post-test questionnaire was completed in both groups, and also a month later, it will be completed again. To measure the change in behavior, telephone follow-up after delivery will be done in both groups.

Participants/Inclusion and exclusion criteria

History of cesarean section; age 18 to 35 years old; single pregnancy; gestational age 26- 34 weeks. No medical indication for cesarean section; no underlying mental illness; no vertical incision on the abdomen. Exclusion criteria: absence from more than one training session.

Intervention groups

Research community in two groups: the intervention who received theory-based training and the control group who received routine training.

Main outcome variables

Intention of Vaginal Delivery after cesarean (VBAC); doing VBAC

General information

Reason for update

Although the study was not related to the disease, this field was incorrectly completed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200519047509N1**
Registration date: **2020-11-13, 1399/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **1**

Registration date

2020-11-13, 1399/08/23

Registrant information

Name
Tamara Dargahi Khiavi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on the Theory of Planned Behavior on the intention and Behavior of vaginal birth after Previous cesarean among pregnant women referred to health centers in Ardabil.

Public title

The effect of educational intervention based on the Theory of Planned Behavior on the intention and Behavior of vaginal birth after Previous cesarean among pregnant women.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Reading and writing Persian literacy Age range 18 to 35 years Single pregnancy Pregnancy 26 to 34 weeks Lack of medical indications for cesarean section Lack of mental illness No vertical incisions in the abdomen If the cause of previous cesarean section is not present in this pregnancy Having consent to participate in research

Exclusion criteria:

Any disease added to the pregnancy that makes cesarean section unavoidable for the mother Suffering from any complications during pregnancy such as high blood pressure during pregnancy, decolman, fetal death, premature rupture of membrane, preterm delivery Failure to attend more than one training session

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this way, the numbers 1 to 70 are written on separate papers and poured into a bowl. And participants selects one of these papers from inside the bowl. Even numbers will be entered into the control group and odd numbers will be assigned to the intervention group.

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

Emergency Alley, Resalat Blvd., Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-05-13, 1399/02/24

Ethics committee reference number

IR.UMSU.REC.1399.037

Health conditions studied

1

Description of health condition studied

Vaginal delivery after a history of cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intention to have a normal delivery

Timepoint

At the beginning of the study (before the intervention), the last session of the intervention and one month after the intervention

Method of measurement

Researcher-made validity and reliability questionnaire

2

Description

Behavior of normal delivery after a history of cesarean section

Timepoint

At the beginning of the study (before the intervention), the last session of the intervention and one month after the intervention

Method of measurement

Researcher-made validity and reliability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for the intervention group, face-to-face training will be arranged in 4 training sessions, which are held once a week. Training classes will be held in groups of 7 to 10 people so that group discussions are possible. The educational content of all groups will be the same and will be adjusted based on the needs assessment of the analysis of pre-test results. The educational content will be based on the structures of the theory of planned behavior. The time of face-to-face training will be 90 minutes. It will include topics related to the advantages and disadvantages of each of the cesarean delivery methods and VBAC, etc. Also, educational pictures and videos related to the delivery process will be used for training. In the last session of the educational intervention, the post-test questionnaire was completed in both intervention and control groups, and also a month later, it will be completed again in both groups. To measure the change in behavior, telephone follow-up of the type of delivery after delivery will be done in both groups.

Category

Other

2

Description

Control group: this group receives prenatal routine trainings. In addition, in order to observe research ethics, at the end of the intervention, a training session is held to observe research ethics and a pamphlet containing educational content is delivered to this group. Corona hygiene will be observed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ardabil city health center

Full name of responsible person
Mohammad Reza Khalfizadeh

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Web page address
http://arums.ac.ir/cityhealth/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Iraj Mohebbi

Street address
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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
Urmia 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
Tamara Dargahi

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
After identifying the completed questionnaires before and after the intervention, the target group will be provided to the ethics committee and will be kept in a safe place for a limited time....
When the data will become available and for how long
5 years
To whom data/document is available
Research team and esteemed members of the University Ethics Committee
Under which criteria data/document could be used
Only for members of the research team and inspectors of the ethics committee for verification
From where data/document is obtainable
Tamara Dargahi
What processes are involved for a request to access data/document
Contact and coordinate with all members of the research team
Comments