

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of education based on the theory of planned behavior on the choice of painless delivery with epidural analgesia in primiparous women.

Protocol summary

Study aim

The aim of this study was to determine The effect of education based on the theory of planned behavior on the choice of painless delivery in primiparous women.

Design

Two arm parallel group randomised trial' not blinded, sample size of 90 people.

Settings and conduct

the statistical population consisted 90 pregnant women referred to Taleghani hospital in Arak who are selected by convenience sampling. After completing the questionnaire of fear of delivery and obtaining a score of more than 28, the samples are included in the study and the questionnaire, which in based on the theory of planned behavior, is completed by samples .Then, with a pot sampling 45 people are selected for each group. In the intervention group educational content based on the theory of planned behavior, including knowledge, attitudes, subjective norms, perceived behavioral control and behavioral intention, to choice of painless delivery, as well as face to face training, and both the training pamphlet and educational DVD/CD offered and at the end two months after intervention, the questionnaire will be filled by pregnant women participating and training package will be given to the control group.

Participants/Inclusion and exclusion criteria

inclusion criteria: pregnant women with child birth fear score 28 or higher, pregnant women at 28-36 weeks of pregnancy, prim gravid singleton women. exclusion criteria: unwillingness to continue to participate in the study

Intervention groups

1-(Intervention group) Presenting four sessions of 90 minutes in-person training in accordance with the educational needs of the pregnant women by pamphlet and educational CD by the researcher. 2-(control group)During the study, they receive routine pregnancy training.

Main outcome variables

Percentage of people who choose painless delivery with epidural analgesia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040544N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Fatemeh Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4446 2166

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on the theory of planned behavior on the choice of painless delivery with epidural analgesia in primiparous women.

Public title

The effect of education on the choice of painless delivery in primiparous women.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

inclusion criteria: pregnant women with child birth fear score 28 or higher pregnant women at 28-36 weeks of pregnancy. prim gravid singleton women.

Exclusion criteria:

unwillingness to participate in the study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, a pot sampling method will be used. In this way, 45 papers are labeled "intervention" and 45 other words are written as "non-intervention". The paper is then placed in a sealed envelope, and individuals randomly select a paper and will be placed in the test or control group. The randomization unit will be in this method individually.

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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Sq.,

Sardashat, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ARAKMU.REC.1397.018

Health conditions studied**1****Description of health condition studied**

Single spontaneous delivery

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

Primary outcomes**1****Description**

Percentage of people who choose painless delivery with epidural analgesia.

Timepoint

Before and after the intervention

Method of measurement

The questionnaire is based on the theory of planned behavior.

Secondary outcomes**1****Description**

Knowledge

Timepoint

Before and after the intervention

Method of measurement

The questionnaire is based on the theory of planned behavior.

2**Description**

Attitudes

Timepoint

Before and after the intervention

Method of measurement

The questionnaire is based on the theory of planned behavior.

3**Description**

Subjective norms
Timepoint
Before and after the intervention
Method of measurement
The questionnaire is based on the theory of planned behavior.

4

Description
perceived behavioral control
Timepoint
Before and after the intervention
Method of measurement
The questionnaire is based on the theory of planned behavior.

5

Description
behavioral intention
Timepoint
Before and after the intervention
Method of measurement
The questionnaire is based on the theory of planned behavior.

Intervention groups

1

Description
Presenting four sessions of 90 minutes in-person training in accordance with the educational needs of the pregnant women by pamphlet and educational CD by the researcher.
Category
Other

2

Description
Control group: During the study, they receive routine pregnancy training.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Fatemeh Khosravi
Street address
Ayatollah Taleghani Hospital, Imam Khomeini street, Arak
City
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3816149369
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad arjmandzadeghan
Street address
Education and Research Deputy, Campus Training Complex, Basij Square
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Email
mmatinam81@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Doctor Mahboobeh Khorsandi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion

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School of Public Health, Golestan Alley, Town Mostafa Khomeini, Arak

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Person responsible for scientific inquiries

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Associate professor

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

If necessary, with the funding of the Arak University of Medical Sciences deputy research, after obtaining a license, will be presented.

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

The study protocol will be presented in the form of a file, and only part of the original outcome data can be shared.

When the data will become available and for how long

The start of the access period is six months after the publication of the results.

To whom data/document is available

Researchers at universities' can apply for them.

Under which criteria data/document could be used

To study and use as a guide.

From where data/document is obtainable

Contact the researcher by email:
f.khosravi95@arakmu.ac.ir

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

Two weeks after the email is received by the researcher, the documentation file is sent to the applicant.

Comments