Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

f.khosravi95@arakmu.ac.ir

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

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3816149369

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It-taleghani@arakmu.ac.ir

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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3848176941

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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

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

Street address
School of Public Health, Golestan Alley, Town Mostafa Khomeini, Arak
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Doctor Mahboobeh Khorsandi
Position
Associate professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Fatemeh Khosravi
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Masters student
Latest degree
Bachelor
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khosravif73@yahoo.com

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