Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of health education based on theory of planned behavior on fear of natural childbirth in pregnant women

Protocol summary

Summary

The aim of this study was to determine the effect of education based on the theory of planned behavior on childbirth fear rate. (Inclusion criteria:The absence of mental diseases , high-risk pregnancy, pregnant women with no history of previous cesarean section, pregnant women at 28-36 weeks of pregnancy, pregnant women with fear score 28 or higher. Exclusion criteria: absence of women in ongoing training sessions (absence in more than one session of educational intervention sessions) , unwillingness to continue to participate in the study, the women's who did not access to post-test questionnaire. In the beginning, from four health care centers in four different areas of The Aleshtar city, intervention group and the control group of 50 people for each of the groups shall be elected randomly. 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 reduce fear of childbirth, as well as training by lecture and group discussion, and both the manual and the training pamphlet offered and at the end of three months after spacing, The questionnaire will be filled by pregnant women participating and training package will be given to the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120625399N1**
Registration date: **2016-06-05, 1395/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-05, 1395/03/16

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of health education based on theory of planned behavior on fear of natural childbirth in pregnant women

Public title

The impact of education through lectures, question and answer on the fear of natural childbirth in pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:The absence of mental diseases , high-risk pregnancy, pregnant women with no history of

previous cesarean section, pregnant women at 28-36 weeks of pregnancy, pregnant women with fear score 28 or higher. Exclusion criteria: absence of women in ongoing training sessions (absence in more than one session of educational intervention sessions) , unwillingness to continue to participate in the study, the women's who did not access to post-test questionnaire.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij Sq., Sardashat, Arak

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Arak

Postal code
00983818146851

Approval date
2015-07-05, 1394/04/14

Ethics committee reference number
IR.ARAKMU.REC.1394.166

Health conditions studied

empty

Primary outcomes

1

Description
Reducing fear of childbirth

Timepoint
Before and after the intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Knowledge, attitudes, subjective norms, perceived behavioral control and behavioral intention

Timepoint
Before and after the intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
" Intervention group : According to the need assessment done to provide educational materials And in-person with booklets and pamphlets to pregnant women by the researcher and through lectures, question and answer and discussion ."

Category
Prevention

2

Description
"Control group: After the intervention, a brief leaflet samples from a control group provided educational materials to pregnant women."

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Lorestan University of Medical Sciences

Full name of responsible person
MonirYosefvand

Street address
Kamalvand, Khoramabad

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Aleshtar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences , Vice chancellor for research

Full name of responsible person
Mohammed Rafeie
Street address
Department of Education and Research, training Integrated Campus, Mobilization
City
Arak
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 , Vice chancellor for research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty