Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education courses to pregnant women and their husbands with previous adverse outcomes on the quality of life and maternal – fetal attachment of pregnant women with previous adverse outcomes, RCT.

Protocol summary

Summary

Title of proposal: The effect of education courses on pregnant women and their husbands with previous adverse outcomes on the quality of life and maternal – fetal attachment of pregnant women with previous adverse outcomes, RCT. Randomized controlled clinical trials Inclusion Criteria in pregnant women: 1.Pregnant women at 24-28 weeks 2.Pregnant women at sarab health centers have mirage health records 3.Hahving at least a third literacy 4.Previous history of adverse consequences in pregnancy such as preterm delivery, low birth weight, stillbirth, miscarriage, neonatal death 5.Consent to participate in the project 6.Having a singleton pregnant women 7.Age 35- 18 years 8.The Edinburgh depression score less than 12 9.To participate in other similar studies Inclusion Criteria in fathers: 1.Hahving at least a third literacy 2.Consent to participate in the project 3.The Edinburgh depression score less than 12 4.Having healthy physical, mental, according to the individual Exclusion Criteria in pregnant women: 1.Mothers with unwanted pregnancies 2.Mothers who want to shift to another place during pregnancy 3.Having a close death, divorce and other serious emotional problems in the past month 4. history of gestational diabetes, preeclampsia, high blood pressure or any other condition that affect maternal health 5.Known to have psychological problems, according to his mother 6.Having fetal malformations and other fetal complications in the current pregnancy 7.Pregnant women who attended prenatal classes intervention: Holding four education courses for mothers on the quality of life and two education courses for mothers and their husbands on the maternal -fetal attachment time of intervention: Pregnant women at 24-28 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601043027N30**
Registration date: **2016-04-04, 1395/01/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-04, 1395/01/16

Registrant information

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Fahimeh Sehhatie Shafaie
Name of organization / entity
Tabriz university of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, tabriz University of Medical Sciences

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-05-26, 1395/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of education courses to pregnant women and their husbands with previous adverse outcomes on the quality of life and maternal – fetal attachment of pregnant women with previous adverse outcomes, RCT.

Public title
The effect of education courses to pregnant women and their husbands on the quality of life and maternal – fetal
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria in pregnant women: .Pregnant women at 24-28 weeks 2.Pregnant women at sarab health centers have mirage health records 3.Hahving at least a third literacy 4.Previous history of adverse consequences in pregnancy such as preterm delivery, low birth weight, stillbirth, miscarriage, neonatal death 5.Consent to participate in the project 6.Having a singleton pregnant women 7.Age 35- 18 years 8.The Edinburgh depression score less than 12 9.To participate in other similar studies Inclusion Criteria in fathers: 1.Hahving at least a third literacy 2.Consent to participate in the project 3.The Edinburgh depression score less than 12 4.Having healthy physical, mental, according to the individual Exclusion Criteria in pregnant women: 1.Mothers with unwanted pregnancies 2.Mothers who want to shift to another place during pregnancy 3.Having a close death, divorce and other serious emotional problems in the past month 4. history of gestational diabetes, preeclampsia, high blood pressure or any other condition that affect maternal health 5.Known to have psychological problems, according to his mother 6.Having fetal malformations and other fetal complications in the current pregnancy 7.Pregnant women who attended prenatal classes
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: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Block design

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz University of Medical Sciences
Street address
azadi AVE, golgasht Ave,Central Building University of Medical Sciences, tabriz, iran.
City
tabriz
Postal code
Approval date
2016-01-18, 1394/10/28
Ethics committee reference number
tbzmed.rec.1394.969

Health conditions studied

1

Description of health condition studied
quality of life and maternal- fetal attachment in pregnant women
ICD-10 code
094-099
ICD-10 code description
Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description
quality of life of pregnant women and maternal - fetal attachment
Timepoint
previous of intervention and one month after intervention
Method of measurement
sf-36 for quality of life and Cranley MFA Scale

Secondary outcomes

1

Description
anxiety
Timepoint
previous of intervention and one month after intervention
Method of measurement
State-Trait Anxiety Inventory Spielberger questioner

Intervention groups

1

Description
control group: Routine care during pregnancy
Category
Prevention

2

Description
Intervention group : : Holding four education courses for mothers on the quality of life and two education courses for mothers and their husbands separatly on the maternal -fetal attachment for 60-90 minutes.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sarab city health center
Full name of responsible person
bita asgharian
Street address
motahhari avenue- sarab
City
sarab

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of tabriz University of Medical Sciences
Full name of responsible person
dr mirghafourvand
Street address
shariaty ave, tabriz,iran
City
tabriz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of tabriz University of Medical Sciences
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

Contact
Name of organization / entity
faculty of nursing and midwifery
Full name of responsible person
fahimeh sehhatie shafaie
Position
Assistant Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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