

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

sehhatief@tbzmed.ac.ir

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: 1. Pregnant women at 24-28 weeks 2. Pregnant women at sarab health centers have mirage health records 3. Having 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. Having 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 separately 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 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