Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of counseling on the maternal- fetal attachment among women with unintended pregnancy: a randomized controlled trial

Protocol summary

Summary

Objectives: To determine the effect of counseling on maternal-fetal attachment in women with unintended pregnancy. Design: Two-armed randomized controlled trial. Conduct: This study will be conducted on women with unintended pregnancy at the ages between 15-49 years old. The researcher will refer to the health centers of Ardabil and will provide a list of women with unintended pregnancy in 18-24 weeks of gestational age, then will call them and if they comply with the eligibility criteria and have tendency to participate in study, they will be invited to be present at the health center. Pre-test questionnaires will be completed and maternal-fetal attachment questionnaire will be analyzed and women with low and middle score will be included in the study. Then women will be randomly assigned into two groups (one group receiving counseling about attachment and one control group) through block randomization with block sizes of four and six. Participants: 80 women with unintended pregnancy ages 15-49 years old. Interventions: For intervention group, six group sessions once a week in six consecutive weeks and 1 to 3 sessions individual counseling about topics of Changes in pregnancy, fetal growth and development, nutrition, the importance of maternal-fetal attachment, fetal movement counting, the image of the fetus and etc. will be provided. The main outcome variable is maternal-fetal attachment and secondary outcomes are depression and anxiety that will be assessed before and 4 weeks after the end of intervention by questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122710324N36**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology University Tabriz Medical Science

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of counseling on the maternal- fetal attachment among women with unintended pregnancy: a randomized controlled trial

Public title

Effectiveness of counseling on the maternal- fetal attachment among women with unintended pregnancy

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Singleton pregnancy; gestational age over than 18 weeks; Having no obstetrics problems (threatened abortion, signs of preterm labor, Preeclampsia, bleeding); Unwanted or mistimed pregnancy. Exclusion criteria: History of mental illness or having it currently; History of diabetes; high blood pressure, bleeding, premature delivery or affected by them currently; Using Psychiatric drugs or Psychoactive substances; History of marital disorders or problems according to the expression of women
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Ethics committee of Tabriz Univercity of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan
City
Tabriz
Postal code
Approval date
2017-01-23, 1395/11/04
Ethics committee reference number
IR.TBZMED.REC.1395.1104

Health conditions studied

1

Description of health condition studied
Unintended Pregnancy
ICD-10 code
Z64.0
ICD-10 code description
Problems related to unwanted pregnancy

Primary outcomes

1

Description
Maternal-fetal attachment
Timepoint
Before intervention and four weeks after the end of intervention
Method of measurement
Materna-fetal attachment questionnaire

Secondary outcomes

1

Description
Depression
Timepoint
Before intervention and four weeks after the end of intervention
Method of measurement
Edinburgh depression scale

2

Description
Anxiety
Timepoint
Before intervention and four weeks after the end of intervention
Method of measurement
Spielberger State-Trait Anxiety Inventory (STAI)

Intervention groups

1

Description
The intervention group will receive six group sessions once a week in six consecutive weeks and 1 to 3 sessions individual counseling about topics of Changes in pregnancy, fetal growth and development, nutrition, the importance of maternal-fetal attachment, fetal movement counting, the image of the fetus and etc.
Category
Behavior

2

Description
The control group will receive standard prenatal cares.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers of Ardabil
Full name of responsible person
Fatemeh Ekrami
Street address
Health centers, Ardabil city, Ardabil province
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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, 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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Ekrami
Position
MSc student in counseling in Midwifery
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Dr. Mojgan Mirghafourvand
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Person responsible for updating data

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Web page address

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