

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

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 University 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

Street address

Nursing & Midwifery Faculty, South Shariati Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3477 2699

Fax

Email

fatemeh.ekrami@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Other areas of specialty/work

Street address

Nursing & Midwifery Faculty, South Shariati Street, Tabriz

City

Tabriz

Postal code

Phone

Fax

Email

Mirghafourvandm@tbzmed.ac.ir;

mirg1385@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Other areas of specialty/work

Street address

Nursing & Midwifery Faculty, South Shariati Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3479 7712

Fax

Email

Mirghafourvandm@tbzmed.ac.ir;
mirg1385@yahoo.com

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