

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cognitive- behavioral therapy on fetal maternal attachment in unwanted pregnancy

Protocol summary

Summary

This study has been done to determine the effectiveness of CBT on fetal maternal attachment in unintended pregnancy. Inclusion criteria are unintended pregnancy; low risk pregnancy; having at least primary education; gestational age between 22-28 weeks; singleton pregnancy; not having fetal death history; not having abortion history; not having mental disorder history. Exclusion criteria are continuous absence in cognitive behavioral therapy sessions; not fill out the follow-up questionnaire; severe pregnancy`s problems; severe anxiety. This study is a clinical trial consisting of 60 pregnant women. women with unintended pregnancies who gestational age is between 22-28 were randomly placed into two groups (case and control). Each group is included 30 members. Members of the two groups at the first meeting fill up the fetal maternal attachment cranley questionnaire. The case group will participate in 4 cognitive-behavioral group therapy sessions, and the control group receive routine pregnancy care. after the last session of therapy, the female participants will be asked to answer the post-test questionnaire, and the results will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092930048N1**

Registration date: **2017-08-01, 1396/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-01, 1396/05/10

Registrant information

Name

zohre ghseminasab

Name of organization / entity

Shahroud university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3279 4679

Email address

ghaseminasab@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2016-06-22, 1395/04/02

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive- behavioral therapy on fetal maternal attachment in unwanted pregnancy

Public title

The effect of counseling on fetal maternal attachment in unwanted pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclsion criteria: unintended pregnancy; low risk pregnancy; having at least primary education; gestational age between 22-28 weeks; singleton pregnancy; not having fetal death history; not having

abortion history; not having mental disorder history
Exclusion criteria: continuous absence in cognitive behavioral therapy sessions; not fill out the follow-up questionnaire; severe pregnancy's problems; severe anxiety

Age

From **15 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shahroud University of Medical Sciences

Street address

Central building of Shahroud University of Medical Sciences, HafteTirSquare, Shahroud

City

Shahroud

Postal code

3614773947

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

ir.shmu.rec.1395.22

Health conditions studied

1

Description of health condition studied

The effect of cognitive- behavioral therapy on fetal maternal attachment in unwanted pregnancy

ICD-10 code

026.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

Fetal maternal attachment

Timepoint

Before and after intervention

Method of measurement

Cranley's fetal maternal attachment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group attend 4 cognitive-behavioral therapy sessions. The intervention method is cognitive behavioral group therapy. session has a certain structure

Category

Treatment - Other

2

Description

The control group receive routine pregnancy care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban health center

Full name of responsible person

Zohre ghaseminasab

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Central building of Shahroud University of Medical Sciences, HafteTirSquare, Shahroud

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research; Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammadhasan Emamian

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Central building of Shahroud University of Medical

Sciences, HafteTir Square, Shahroud
City
 Shahroud
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; Shahroud 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
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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