

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of cognitive behavior therapy on women's anxiety with unintended pregnancy

Protocol summary

Summary

This study was aimed at determining the effectiveness of CBT on women's anxiety with unintended pregnancy. The inclusion criteria were low-risk pregnancy, unintended pregnancy and the Beck's anxiety score 14 to 30. The exclusion criteria were the lack of cooperation, abortion, referral or treatment for other problems which the research participants faced, and severe anxiety and depression. This study is a clinical trial consisting of 30 multiparous women. Multiparous women with low-risk pregnancies who were in the first half of pregnancy were randomly placed into two groups (case and control). Each group included 15 members. The case group underwent 8 cognitive-behavioral group therapy sessions, and the control group received routine pregnancy care. In this study, the intervention method used to control the anxiety of women in unintended pregnancy was a cognitive-behavioral therapy, which was held in eight 90-minute sessions. Each therapy session had a specific structure. One week after the last session of therapy, the Beck's anxiety questionnaire was filled out by the female participants, and the results were compared with each other. The primary outcome of this study was reducing anxiety of unintended pregnancy among multiparous women in terms of the score obtained from the Bek anxiety questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120920252N1**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name

Omekolsum Tabarteh Farahani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive behavior therapy on women's anxiety with unintended pregnancy

Public title

The effect of cognitive behavior therapy on women's anxiety with unintended pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: fill out the form of informed consent;

eighteen to forty years old; high school diploma; unintended pregnancy; multiparity; gestational age is lower than twenty weeks; low risk pregnancy and normal BMI; dont have severe depression and anxiety according to the Beck`s questionnaire; not using psychiatric drugs; anxiety score is 14 to 30 and dont havefamily conflicts. Exclusion criteria: willingness to participate in the other treatment and non- cooperation; continuous absence in cognitive behavioral therapy sessions; not fill out the follow-up questionnaire; severe pregnancy`s problems for mothers.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Arak University of Medical Sciences

Street address

Sardasht Avenue, Basij Square, Arak, Markazi Province, Iran

City

arak

Postal code

Approval date

2015-06-08, 1394/03/18

Ethics committee reference number

IR.ARAKMU.REC.1394.50

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.3

ICD-10 code description

Other mixed anxiety disorders

Primary outcomes

1

Description

anxiety

Timepoint

Before intervention; one week after intervention

Method of measurement

Beck`s Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The control group receive routine antennal care

Category

N/A

2

Description

The intervention group attend eight cognitive-behavioral therapy sessions. The intervention method is cognitive behavioral group therapy. Eight group sessions is held during second trimester. Each ninety minutes session has a certain structure

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers Aristotle

Full name of responsible person

Naimeh Akbari Torkestani

Street address

Health centers Aristotle, 15 yards of Khatam, 30 yards of Emam Ali. Arak.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Arak University of
Medical Sciences

Full name of responsible person

Naeimeh Akbari Torkestani

Street address

Sardasht Avenue, Basij Square, Arak, Markazi

City

Arak

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 Arak 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

Arak University of Medical Sciences

Full name of responsible person

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Position

Senior in midwifery

Other areas of specialty/work

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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