

# 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

2016-11-18, 1395/08/28

#### 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

#### Registrant information

##### Name

Omekolsum Tabarteh Farahani

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3373 0226

##### Email address

o.t.farahani@arakmu.ac.ir

#### 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**

Naeimeh Akbari Torkestani

**Position**

Senior in midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Omm Kolsum Tabarteh Farahani

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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*