

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of Cognitive-Behavioral Stress Management Intervention on Anxiety in pregnancy and Maternal-Fetal attachment

#### Protocol summary

##### Summary

This clinical trial is performed to determine the effectiveness of cognitive-behavioral stress management skills training on anxiety during pregnancy and maternal-fetal attachment. Inclusion criteria: age between 18 to 35 years old; first pregnancy; 14 to 28 weeks gestational age based on the date of the first day of the last menstrual period; moderate or severe anxiety based on Beck Anxiety Inventory; ability to read and write; low-risk pregnancy; no history of significant mental and physical chronic diseases such as diabetes, cardiovascular disease and depression; avoiding the use of chemical or herbal anti-anxiety drugs and sedatives. Exclusion criteria: not wanting to take part in training sessions; complication of pregnancy that resulted in the inability of the mother to participate in class; medication to reduce anxiety; specialized counseling psychology and absence more than 3 times in educational sessions. The study population included all pregnant women referred to clinic of Imam Khomeini hospital of Khomein city, Iran. Thirty pregnant women eligible will be randomly divided into two groups (Intervention and control). Stress management skills training classes, 10 sessions (2 sessions per week) for 90 minutes for intervention group to be held. Evaluation 2 weeks after the meetings by Beck Anxiety Inventory and kranly Mother - fetal attachment questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015111124997N1**  
Registration date: **2015-12-08, 1394/09/17**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-12-08, 1394/09/17

##### Registrant information

###### Name

Mobina Poormohammadi

###### Name of organization / entity

Arak university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 4622 7723

###### Email address

m.pormohammadi@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2016-01-20, 1394/10/30

##### Expected recruitment end date

2016-06-19, 1395/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Cognitive-Behavioral Stress Management Intervention on Anxiety in pregnancy and Maternal-Fetal attachment

##### Public title

Effectiveness of Cognitive-Behavioral Stress Management Intervention on Anxiety in pregnancy and Maternal-Fetal attachment

##### Purpose

Health service research

## **Inclusion/Exclusion criteria**

Inclusion criteria: age between 18 to 35 years old; first pregnancy; 14 to 28 weeks gestational age based on the date of the first day of the last menstrual period; moderate or severe anxiety based on Beck Anxiety Inventory; ability to read and write; low-risk pregnancy; no history of significant mental and physical chronic diseases such as diabetes, cardiovascular disease and depression; avoiding the use of chemical or herbal anti-anxiety drugs and sedatives. Exclusion criteria: not wanting to take part in training sessions; complication of pregnancy that resulted in the inability of the mother to participate in class; medication to reduce anxiety; specialized counseling psychology and absence more than 3 times in educational sessions.

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Female

### **Phase**

N/A

### **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**

research center of arak university of medical sciences

##### **Street address**

Basij Square , on the campus of the University of Medical Sciences - Department of Education and Research

##### **City**

arak

##### **Postal code**

38481-7-6941

##### **Approval date**

2015-09-14, 1394/06/23

##### **Ethics committee reference number**

ir.arak.mu.rec.1394.177

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

pregnancy

#### **ICD-10 code**

Z34

#### **ICD-10 code description**

Supervision of normal pregnancy

### **2**

#### **Description of health condition studied**

Anxiety

#### **ICD-10 code**

F41.1

#### **ICD-10 code description**

Generalized anxiety disorder

### **3**

#### **Description of health condition studied**

maternal - fetal attachment

#### **ICD-10 code**

P00

#### **ICD-10 code description**

Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy

## **Primary outcomes**

### **1**

#### **Description**

Anxiety

#### **Timepoint**

Before intervention , Two weeks after the end of intervention

#### **Method of measurement**

Beck Anxiety Inventory

### **2**

#### **Description**

Maternal - fetal attachment

#### **Timepoint**

Before intervention , Two weeks after the end of intervention

#### **Method of measurement**

Kranly maternal - fetal Attachment Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group : cognitive- behavioral stress

management skills training , 10 sessions , 2 times a week , every 90 minutes

**Category**

Behavior

**2**

**Description**

Control group : No action

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of Imam Khomeini Hospital

**Full name of responsible person**

Mobina Poormohammadi

**Street address**

**City**

Khomein

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Nafisa Seyedzadeh

**Street address**

Arak University of Medical Sciences, Basij square

**City**

Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Mobina Poormohammadi

**Position**

Consultation in Midwifery MSc student

**Other areas of specialty/work**

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**Fax**  
**Email**  
**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*