

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

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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

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Mobina Poormohammadi

Position

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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