Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cognitive- behavioral education on pregnant women’s anxiety with positive results of screening for chromosomal abnormalities

Protocol summary

Study aim
Determining the effect of cognitive- behavioral education on pregnant women's anxiety with positive result of Screening for abnormalities

Design
Randomized clinical trial

Settings and conduct
Counseling room in the perinatal clinic of Shahid Akbarabadi hospital which will be provided to the researcher in coordination with the hospital. . The researcher provides the welfare and health conditions and facilities (disinfection equipment and the appropriate distance between the researcher and the client and that the training classes are held individually).

Participants/Inclusion and exclusion criteria
Inclusion criteria - Being Iranian - Being the Persian language - gestational age 11-15 weeks - Primiparous women - Single pregnancy - State anxiety score between 31 to 75 and trait anxiety score between 31 to 72 - Have at least primary school - Full alertness and acceptable listening and speaking ability to receive education and answer questions Exclusion criteria - The history of infertility - History of serious psychiatric disorders including psychotic, bipolar and depression

Intervention groups
In the experimental group, 4 sessions of individual counseling are held for 90 minutes, two sessions a week. The first session includes explanations about the importance, features, benefits, risks and differences between screening tests in the first and second trimesters and relaxation. The second session includes misconceptions about the cause of screening anxiety, as well as A-B-C chain training. The third session includes training the presence of mind and strengthening the positive thoughts of the mother. The fourth session is a program of spontaneous change of thinking and behavior, cognitive errors. In the control group, participants will receive routine pregnancy care. Anxiety questionnaire will be completed before and at the end of the intervention.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180427039436N7**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **prospective**

Last update: **2020-08-24, 1399/06/03**
Update count: **0**

Registration date
2020-08-24, 1399/06/03

Registrant information

Name
Leila Amiri Farahani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4365 1139

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive- behavioral education on pregnant women’s anxiety with positive results of screening for chromosomal abnormalities

Public title

The effect of cognitive- behavioral education on pregnant women’s anxiety with positive results of screening for chromosomal abnormalities

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Being Persian language gestational age 11-15 weeks Primiparous women Single pregnancy State anxiety score between 31 to 75 and trait anxiety score between 31 to 72 Have at least primary school Full alertness and acceptable listening and speaking ability to receive education and answer questions

Exclusion criteria:

History of infertility History of serious psychiatric disorders including psychotic, bipolar and depression

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, a quadratic block randomization method will be used by the randomization.com site.

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 Iran University of Medical Sciences

Street address

Rashid yasemi

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2020-08-18, 1399/05/28

Ethics committee reference number

IR.IUMS.REC.1399.433

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

According to Kaylan and Zadok, anxiety is a diffuse, very unpleasant feeling, often accompanied by vague anxiety that is accompanied by one or more physical feelings; Symptoms such as chest tightness, palpitations, sweating, headaches, sudden urge to urinate, restlessness, and a desire to move are also common symptoms.

Timepoint

Before the intervention and after the end of the intervention.

Method of measurement

Spielberger state-trait anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, 4 sessions of individual counseling are held for 90 minutes, two sessions a week. The first session includes introduction and expression of clients' feelings about the screening result and educational content including explanations about the importance, features, benefits, risks and differences between screening tests in the first and second trimesters and relaxation and homework training. The second session includes a review of the previous session's assignments and misconceptions about the cause of screening anxiety, as well as A-B-C chain

training and homework. The third session includes reviewing the assignments of the previous session and training the presence of mind and strengthening the positive thoughts of the mother and homework.

Category

Behavior

2

Description

Control group: In the control group, people will receive routine pregnancy care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Arezoo Bayat

Street address

Molavi Street, not far from Molavi Crossroads, Ferdows Garden Station

City

Tehran

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Postal code

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+98 21 5560 8012

Email

Akbarabadihosp@yahoo.com

Web page address

Http://www.crta.iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Shahid Hemmat highway, District 2

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Tehran

Province

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Postal code

1449614535

Phone

+98 21 6650 9024

Fax

+98 21 8805 2248

Email

Motevalian.a@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Associate

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
it is not available
When the data will become available and for how long
it is not available
To whom data/document is available
it is not available
Under which criteria data/document could be used
it is not available
From where data/document is obtainable
it is not available
What processes are involved for a request to access data/document
it is not available
Comments
it is not available