Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of CBT and Attentional Bias Modification on the Anxiety of the Pregnant Women: A Comparative Study

Protocol summary

Study aim

Comparison of effectiveness of Cognitive-behavioral Therapy (CBT) and Attentional Bias Modification (ABM) on the Anxiety of the Pregnant Women

Design

A clinical trial with a control group, with parallel groups, multi-stage random, with 72 participants in the study, was followed from July 1 to December 2016 for six months.

Settings and conduct

This study was performed on 72 pregnant nulliparous women referring to health centers in Kerman. from the four regions of Kerman city, region three was selected by random and then among the health centers of this area, three main clinics were selected randomly. Samples were assigned random to each of three groups including CBT, ABM and control. in each of these clinics, demographic questionnaire and Spielberger anxiety questionnaires were completed by pregnant women who were referred to these clinics. The sample size was obtained by convenient sampling at this stage. The eligible participants entered in the study after obtaining informed consent. CBT group was exposed to six two-hour sessions per week. The ABM group received intervention using the modified dot-probe task at six sessions, one session per week and the control group did not receive any intervention. To collect the data, the questionnaires were completed three times: before the intervention, immediately after the intervention and one month after intervention. Data were analyzed using SPSS version 22 and descriptive and Inferential Statistical Indices.

Participants/Inclusion and exclusion criteria

age between 18-35 years؛ primigravid؛ gestational age 14-28 weeks؛ low-risk pregnancy؛ desired pregnancy؛ low to moderate anxiety scores؛ having at least a middle school education؛ willing to attend the educational sessions and ability of doing homework

Intervention groups

CBT Group ABM group Control group

Main outcome variables

Reducing Anxiety in Pregnant Women

General information

Reason for update

Acronym

CBT, ABM

IRCT registration information

IRCT registration number: **IRCT20180922041082N1**
Registration date: **2019-01-20, 1397/10/30**
Registration timing: **retrospective**

Last update: **2019-01-20, 1397/10/30**
Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Masoud Fazilat-Pour

Name of organization / entity

Shiraz University

Country

Iran (Islamic Republic of)

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+98 34 3613 4670

Email address

fazilatm@uk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

2016-06-21, 1395/04/01

Actual recruitment end date

2016-07-22, 1395/05/01

Trial completion date

2016-12-20, 1395/09/30

Scientific title

Effectiveness of CBT and Attentional Bias Modification on the Anxiety of the Pregnant Women: A Comparative Study

Public title

Effectiveness of CBT and Attentional Bias Modification on the Anxiety of the Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-35 years primigravid gestational age 14-28 weeks low-risk pregnancy desired pregnancy low to moderate anxiety scores having at least a middle school education willing to attend the educational sessions ability of doing homework

Exclusion criteria:

pregnancy complications such as bleeding, diabetes, hypertension, preterm delivery and internal illness use of anxiolytics and anti-depressants having encountered with severe stress during the intervention period e.g., the death of first-degree relatives, divorce, spouse in prison.

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: **75**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi stage randomization: In order to facilitate the access to sampling units and from the four regions of Kerman city, region three was selected by random sampling. Then, three main clinics were selected randomly among health centers of this area. These three centers were also assigned as two intervention groups and one center as control group. Afterwards, based on the inclusion and exclusion criteria of the study and after obtaining informed consent, eligible participants were entered the study. It should be noted that in all cases of randomization, the lottery method was employed.

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 Kerman University of Medical Sciences

Street address

Medical University Campus, Haft-Bagh Highway, Kerman, Iran.

City

Kerman

Province

Kerman

Postal code

76169-13555

Approval date

2016-06-19, 1395/03/30

Ethics committee reference number

IR.Kmu.REC.1395.93

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety levels in pregnant women

Timepoint

Measure anxiety level before intervention, immediately after intervention, one month after intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Cognitive Behavioral Therapy (six two-hour sessions per week)

Category
Behavior

2

Description
Second intervention group: Attentional Bias Modification (using the modified dot-probe task at six sessions, one session per week, first and sixth sessions for half an hour, and the remaining sessions in about 10 minutes)
Category
Behavior

3

Description
Control group: No intervention received.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghodrat Health Center
Full name of responsible person
Nadia Nisi
Street address
Shaykh Ahmad Kafi North Street
City
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Province
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Web page address

2

Recruitment center
Name of recruitment center
Resalat Health Center
Full name of responsible person
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South Abuzar, Alley 10
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Fax
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3

Recruitment center
Name of recruitment center
Goldasht Health Center
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Setare Nozhati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
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Phone
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
1
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
Kerman University of Medical Sciences
Full name of responsible person
Masoud Fazilatpour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Phone
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Fazilatm@uk.ac.ir

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
the data are collected anonymously
When the data will become available and for how long
in case of request the data are available anonymous
To whom data/document is available
the further researchers with credible studies from reputable constitutions
Under which criteria data/document could be used
researchers with credible studies from reputable constitutions
From where data/document is obtainable
after the article got published
What processes are involved for a request to access data/document
contact with the corresponding author
Comments
no further comments