

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of internet-based emotion-focused cognitive behavior therapy (iECBT) with and without spouse participation on psychological distress and stress in pregnant women with anxiety disorders

Protocol summary

Study aim

Reduction of stress in anxious pregnant women

Design

Intervention group2: The participants in this group receive iECBT without spouse participation once a week, 8 session 1 hour.

Settings and conduct

This study will be conducted on pregnant women who referring to the affiliated hospitals of Babol University of Medical Sciences and private offices of obstetricians and gynecologists. Pregnant women with anxiety disorders allocate randomly into two experimental groups. The participants of group A (42 persons) will receive iECBT with spouse participation. The participants of group B (42 persons) will be received iECBT without spouse participation iCBT sessions are performed for 8 weeks (1 hour session per week), which is done with the participation of the spouse and without the participation of the spouse.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 13-28 weeks, diagnosis of anxiety disorders based on SCID-5, access to computers and the Internet, education level of higher than primary school, consent of the woman and her husband to enter the study. Exclusion criteria: current substance abuse or dependence, currently using of sedatives, Receiving psychotherapy during past six months, women who have an abortion, premature birth, terminated pregnancy during the intervention, women diagnosed with severe anxiety disorders,, severe psychiatric disorders and suicidal ideation.

Intervention groups

Intervention group1: The participants in this group receive iECBT with spouse participation once a week, 8 session 1 hour.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110228005931N10**

Registration date: **2021-09-10, 1400/06/19**

Registration timing: **prospective**

Last update: **2021-09-10, 1400/06/19**

Update count: **0**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effectiveness of internet-based emotion-focused cognitive behavior therapy (iECBT) with and without spouse participation on psychological distress and stress in pregnant women with anxiety disorders
Public title	Effect of internet-based emotion-focused cognitive behavior therapy with spouse participation on stress of anxious pregnant women
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Gestational age of 13-28 weeks Diagnosis of anxiety disorder based on SCID-5 Access to computers and the Internet Education level of higher than primary school consent of the wife and her husband to enter the study
Exclusion criteria:	Current substance abuse or dependence Currently use of sedatives Receive psychotherapy during past months ago Abortion, preterm labor, termination of pregnancy women with severe anxiety disorders who required medical treatment Severe psychiatric disorders and suicidal ideation
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	<i>No information</i>
Sample size	Target sample size: 82
Randomization (investigator's opinion)	Randomized
Randomization description	Eligible participants will allocate randomly two groups (42 individuals) by permuted block randomization method. The block size is 4 and the allocation ratio is 1:1. In each block, intervention groups will be repeated twice. Therefore, we will have 21 different blocks. Then, using the statistical program in R software version 3.6.1, 4 part blocks will be generated 21 times, which will produce a total of 84 sequences.
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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Babol, Iran.

City

Babol

Province

Mazandaran

Postal code

47745-47176

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.MUBABOL.RC.1400.164

Health conditions studied

1

Description of health condition studied

Anxiety disorder

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorderS

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, at end of the intervention, and follow- ups of 1 and 3 months after the end of intervention.

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI)

2

Description

Psychological distress

Timepoint

Before the intervention, at end of the intervention, and follow- ups of 1 and 3 months after the end of intervention.

Method of measurement

Brief Syndrome Inventory (BSI-18)

Secondary outcomes

1

Description

Pregnancy stress

Timepoint

Before the intervention, at end of the intervention, and follow- ups of 1 and 3 months after the end of intervention.

Method of measurement

Revised Prenatal Distress Questionnaire (NuPDQ)

2

Description

Emotion regulation

Timepoint

Before the intervention, at end of the intervention, and follow- ups of 1 and 3 months after the end of intervention.

Method of measurement

Cognitive emotion regulation questionnaire (CERQ)

Intervention groups

1

Description

Intervention group: The participants in this group receive iECBT with spouse participation once a week, 8 session 1 hour.

Category

Treatment - Other

2

Description

Intervention group: The participants in this group receive iECBT without spouse participation once a week, 8 session 1 hour.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Shahnaz Barat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mojgan Shariat Panahi

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BLV. Shahid Fahmideh, BLV. Shahid Beheshti, Saveh, Markazi province, Iran.

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Mojgelita_50@yahoo.com

Grant name

Thesis in PhD degree

Grant code / Reference number

162397152

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Azadeh Farghadani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available