Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of internet-based emotion-focused therapy on anxiety and pregnancy outcomes in anxious women with a suspected fetal malformation

Protocol summary

Study aim
Reduction of anxiety and improvement of pregnancy outcome in women suspected with fetal malformation

Design
The method is a randomized controlled clinical trial with a four-arm parallel type. 140 patients will be included in the study through randomization using R software.

Settings and conduct
140 anxious pregnant women with suspected fetal malformation will be selected from public hospitals and private offices in Babol City. Participants will be divided into four groups in a four-arm parallel randomized clinical trial, including IEFT alone, IEFT combined with a booster dose, IEFT along with spouse participation, IEFT along with spouse participation, and a booster dose. The content of the four types of therapy will be prepared online. The content validity in the therapies will be confirmed by a specialized team. All participants will complete five questionnaires, namely Spielberger's state anxiety, pregnancy-specific stress, uncertainty intolerance questionnaire, emotion regulation, and Edinburgh postnatal depression, before the trial, at the end of the 6-week intervention, 3-month and 6-month post-trial follow-ups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age under 20 weeks, suspected fetal malformation, anxiety score above 30, education level higher than primary school, access to the Internet. Exclusion criteria: Substance abuse, the current use of tranquilizers, severe psychiatric disorders such as severe anxiety, major depression, schizophrenia, bipolar disorder, and suicidal ideation.

Intervention groups
Intervention group 1: only internet-based emotion-focused therapy (IEFT) Intervention group 2: IEFT with reminder dose Intervention group 3: IEFT with spouse participation Intervention group 4: IEFT with both spouse participation and dose reminder

Main outcome variables
Anxiety symptoms, Emotion regulation

General information

Reason for update
In the description of randomization, the sample size was reduced to 140 people. The end time of the study was changed to June 30.

Acronym

IRCT registration information
IRCT registration number: **IRCT20110228005931N11**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-24, 1402/02/04**
Update count: **1**

Registration date
2021-12-22, 1400/10/01

Registrant information

Name
Mahbobeh Faramarzi

Name of organization / entity
Babol University of medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2023-06-30, 1402/04/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of internet-based emotion-focused therapy on anxiety and pregnancy outcomes in anxious women with a suspected fetal malformation

Public title
Effect of internet-based emotion-focused therapy on the anxiety of women with a suspected fetal malformation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age of less than 20 weeks Suspected of fetal malformation based on diagnosis by a gynecologist Spielberger's anxiety score above 30 Educational level higher than primary school Consent of the woman and her husband to enter treatment Access to computers and the Internet
Exclusion criteria:
Current substance abuse Current use of sedative drugs like benzodiazepines, or recent psychotherapy for depression/anxiety (<4 weeks) Severe psychiatric disorders such as severe anxiety, sever depression, and suicidal thought
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **408**
Randomization (investigator's opinion)
Randomized
Randomization description
After checking inclusion and exclusion criteria, participants are allocated randomly into four groups by permuted block randomization method. The block size is 4 and by using the statistical software, Each block of each intervention group will be repeated once, As a result, we will have 35 different blocks, Then, using the statistical program in R software environment version 11, 35 blocks of 4 will be generated, which will produce a total of 140 sequences. Randomization is assigned by standalone statistical software using a computer random sequence to assign participants to one of four study groups using this randomly generated list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features
A randomized controlled clinical trial with four-arm parallel

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran, Babol
City
Babol
Province
Mazandaran
Postal code
47745-47176
Approval date
2021-04-30, 1400/02/10
Ethics committee reference number
IR.MUBABOL.REC.1400.072

Health conditions studied

1

Description of health condition studied
Anxiety disorder
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Anxiety
Timepoint
Before intervention, at the end of intervention (6 weeks post-trial), follow-up of 3 and 6 months after the intervention
Method of measurement
Spielberger's anxiety questionnaire

2

Description
Emotion regulation
Timepoint
Before intervention, at the end of intervention (6 weeks

post-trial), follow-up of 3 and 6 months after the intervention

Method of measurement

Cognitive emotion regulation questionnaire

Secondary outcomes

1

Description

Uncertainty intolerance

Timepoint

Before intervention, at the end of intervention (6 weeks post-trial), follow-up of 3 and 6 months after the intervention

Method of measurement

Uncertainty Intolerance Questionnaire

2

Description

Pregnancy stress

Timepoint

Before intervention, at the end of intervention (6 weeks post-trial), follow-up of 3 and 6 months after the intervention

Method of measurement

Revised Pregnancy Distress Questionnaire (NuPDQ)

3

Description

Depression

Timepoint

Before intervention, at the end of intervention (6 weeks post-trial), follow-up of 3 and 6 months after the intervention

Method of measurement

Edinburgh Postnatal depression questionnaire

Intervention groups

1

Description

In this group, the participants will receive Internet emotion-focused therapy for six 90-minute sessions once a week. During the sessions, participants will interact with the content of the program via videos, text, audio, audio clips, therapist explanations, and relevant practices. During the therapy, patients will acquire necessary skills, including identifying and evaluating thoughts, recognizing emotions, and emotion management skills. Patients' assignments will be online both during the sessions and the week and will be sent to the therapist. The therapist will also reflect feedback on assignments to patients via SMS.

Category

Treatment - Other

2

Description

The participants of the group will be received IEFT(6 sessions of online treatment with duration 90 minutes, once a week) with 6sessions of mreminder dose (after treatment, one session every month for 6 months)

Category

Treatment - Other

3

Description

The participants of the group will be received IEFT(6 sessions of online treatment with duration 90 minutes, once a week) with the participation of their husband during treatment.

Category

Treatment - Other

4

Description

The participants of the group will be received IEFT(6 sessions of an online treatment with duration 90 minutes, once a week) with the participation of their husband during treatment, as well as reminder dose (after treatment, once session every month for 6 months)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

Shahnaz Barat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Grant name
Master of Thesis

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Dr. Mahbobeh Faramarzi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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