

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1329 4456

##### Email address

m.faramarzi@mubabol.ac.ir

##### 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 Spielberg'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

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

**City**

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**Province**

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**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**

Dr.Mahbobeh Faramarzi

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Mahbob330@yahoo.com

**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