

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Effect of internet-based cognitive behavioral therapy in reduction of anxiety/depression of infertile women

#### Protocol summary

##### Study aim

Effectiveness of internet-based cognitive behavioral therapy in reduction of anxiety/depression of infertile women

##### Design

A non-inferiority randomized controlled clinical trial with two parallel arms

##### Settings and conduct

This study will be conducted on infertile women who referring to Fatemeh Zahra infertility center. Infertile women with anxiety/ depression allocate randomly into two experimental groups. The participants of group A (30 persons) will be receive online cognitive behavioral therapy. The participants of group B (30 persons) receive individually face-to-face cognitive behavioral therapy. The contents and structures of two groups are same duration of 8 sessions, once a week, lasting 50 minutes. All patients of two groups will be filled four questionnaires including; 9-questions patient's health questionnaire (PHQ-9), Beck Depression questionnaire, Beck Anxiety questionnaire, Fertility problem inventory and covid-19 anxiety at the beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2) .

##### Participants/Inclusion and exclusion criteria

inclusion criteria: aged 19-45 years, more than five years of education, based on Beck's questionnaire meeting the criteria for mild to moderate depression (between 14 to 49); did not receive any medication or counseling, have access to computers and the Internet, have access to a telephone that is always able to respond. Exclusion criteria include: unwillingness to participate in the study, severe depression, and the existence of suicidal ideation.

##### Intervention groups

Intervention group A will be received online cognitive behavioral therapy. Intervention group B receives individually face-to face cognitive behavioral therapy. The duration of treatment for both groups is similar, 8 sessions, once a week for 50 minutes.

#### Main outcome variables

Anxiety and depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110228005931N9**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

##### Registration date

2020-12-08, 1399/09/18

##### 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

2020-12-05, 1399/09/15

##### Expected recruitment end date

2021-06-22, 1400/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of internet-based cognitive behavioral therapy in reduction of anxiety/depression of infertile women

**Public title**  
Effectiveness of internet psychotherapy in reduction of anxiety/depression of infertile women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Aged 19-45 years More than five years of education  
 Based on Beck's questionnaire meeting the criteria for mild to moderate depression (between 14 to 49) Did not receive any medication or counseling Have access to computers and the Internet Have access to a telephone that is always able to respond  
**Exclusion criteria:**  
 Unwillingness to participate in the study Severe depression The existence of suicidal ideation

**Age**  
From **19 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After checking inclusion and exclusion criteria, participants are allocate randomly into two groups by permuted block randomization method. The block size is 4 and by using the statistical software, 4 part blocks will be produced 15 times. One samples of 60-list will be produced. Using this randomly generated list, participants are divided into two groups of 30 people.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
A non-inferiority randomized controlled clinical trial with two parallel arms

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

National Institute for Medical Research Development (NIMAD)

#### Street address

National Institute for Development of Medical Research (NIMAD), No. 21, Besat St., West Fatemi St., Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۹۶۹۳۱۱۱

#### Approval date

2019-06-16, 1398/03/26

#### Ethics committee reference number

IR.NIMAD.REC.1398.174

## Health conditions studied

1

### Description of health condition studied

Anxiety and depression

#### ICD-10 code

F41.2

#### ICD-10 code description

mixed anxiety and depressive disorder

## Primary outcomes

1

### Description

Anxiety

#### Timepoint

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2) and 6 months

#### Method of measurement

Beck Anxiety questionnaire

2

### Description

Depression

#### Timepoint

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2)

#### Method of measurement

Beck depression questionnaire

## Secondary outcomes

1

### Description

Patient's health

## **Timepoint**

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2)

## **Method of measurement**

9-questions patient's health questionnaire (PHQ-9)

## **2**

### **Description**

Infertility stress

### **Timepoint**

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2)

### **Method of measurement**

Fertility problem inventory

## **3**

### **Description**

Covid-19 anxiety

### **Timepoint**

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2) and 6 months

### **Method of measurement**

Covid-19 anxiety questionnaire

## **4**

### **Description**

Patient treatment satisfaction

### **Timepoint**

beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention (month 2) and 6 months

### **Method of measurement**

Patient treatment satisfaction questionnaire

## **Intervention groups**

## **1**

### **Description**

Intervention group A: The participants in this group receive online cognitive behavioral therapy once a week, 8 session 50 minutes.

### **Category**

Treatment - Other

## **2**

### **Description**

Intervention group B: Participants in this group receive individually face-to-face cognitive behavioral therapy, once a week 8 sessions 50 minutes.

### **Category**

Treatment - Other

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Fatemeh Zahra Fertility and Infertility Center

#### **Full name of responsible person**

Dr. Zahra Basirat

#### **Street address**

Fatemeh Al-Zahra Infertility Center, Tork Mahalle, Amol-Babol Road, Babol City, Mazandaran Province, Iran

#### **City**

Babol

#### **Province**

Mazandaran

#### **Postal code**

47176-47745

#### **Phone**

+98 11 3227 4880

#### **Email**

Zahra\_basirat@yahoo.com

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

National Institute for Medical Research Development (NIMAD)

#### **Full name of responsible person**

mahboobe faramarzi

#### **Street address**

National Institute for Development of Medical Research (NIMAD), No. 21, Besat St., West Fatemi St., Tehran, Iran

#### **City**

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#### **Province**

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#### **Postal code**

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#### **Phone**

+98 11 1329 4456

#### **Email**

mahbob330@yahoo.com

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

National Institute for Medical Research Development (NIMAD)

### **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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Farzan Kheyrkhah

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

shiva shafie rizi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Counseling in Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Farzan Kheirkhah

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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**Postal code**

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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