

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 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 Fertlutu 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

Tehran

Province

Mazandaran

Postal code

۱۴۱۹۶۹۳۱۱۱

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

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 911 112 8368

Email

drfarzankh@yahoo.com

Web page address**Phone**

+98 911 112 8368

Email

drfarzankh@yahoo.com

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

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 913 423 7661

Email

shiva0shafie@gmail.com

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

Street address

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

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