Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 Fertiluty 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

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
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

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