Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of effect of compute-based versus face- to-face cognitive behavioral therapy for improvement of symptoms of adjustment disorders in infertile women

Protocol summary

Study aim

Comparison of the effectiveness of computerized cognitive behavioral therapy with face-to-face cognitive behavioral therapy in improvement of symptoms of adjustment disorders among infertile women

Design

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

Settings and conduct

Infertile women diagnosed as adjustment disorder referred to Fatemeh Zahra infertility center and Mehregan, allocate randomly into two experimental groups.The participants of intervention group 1 will be receive computerized cognitive behavioral therapy and intervention group 2 receive 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 questionnaires Symptoms of adjustment disorder, Hospital anxiety and depression scale, Fertility problem inventory, and Infertility Adjustment Scale, at the beginning of the intervention, 4 weeks after the beginning of the intervention, end of the intervention, 3 months and 6 months follow-ups. a person who is not in research team, will be assessed the outcomes of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 18 years old, at least a third year of middle school, Internet access and the ability to use a computer, not using psychotherapy services right now. Exclusion criteria: people with mental disabilities, severe psychiatric disorders such as severe depression, psychotic disorder, bipolar disorder, suicide risk, drug abuse...

Intervention groups

Intervention group A will be received computerized 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

Symptoms of adjustment disorder, Depression, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110228005931N8**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**
Update count: **0**

Registration date

2020-07-22, 1399/05/01

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

2020-09-22, 1399/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of compute-based versus face- to-face cognitive behavioral therapy for improvement of symptoms of adjustment disorders in infertile women

Public title

Efficacy of computer-based vs face-to face cognitive behavioral therapy in infertile women with adjustment disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years old At least a third year of middle school Internet access and the ability to use of computer No current psychotherapy services

Exclusion criteria:

People with mental disabilities Severe psychiatric disorders such as severe depression Psychotic disorder Bipolar disorder Suicide risk Drug abuse

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

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 38 times. Due to the fact that sampling is done in two centers, two samples of 152-list will be produced. Using this randomly generated list, participants are divided into two groups of 76 people.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Babol University of Medical Sciences

Street address

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

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Postal code

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Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1399.105

Health conditions studied

1

Description of health condition studied

Adjustment disorder

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

Primary outcomes

1

Description

Symptoms of adaptive disorder

Timepoint

Before the intervention, the fourth week after beginning the intervention, at end of the intervention, and follow-ups of 3 and 6 months after the end of intervention

Method of measurement

Adjustment disorder

2

Description

Anxiety

Timepoint

Before the intervention, the fourth week after beginning the intervention, at end of the intervention, and follow-ups of 3 and 6 months after the end of intervention

Method of measurement

Hospital anxiety and depression scale

3

Description

Depression

Timepoint

Before the intervention, the fourth week after beginning the intervention, at end of the intervention, and follow-ups of 3 and 6 months after the end of intervention

Method of measurement

Hospital anxiety and depression scale

Secondary outcomes

1

Description

Infertility stress

Timepoint

Before the intervention, at end of the intervention, and follow- up 6 months after the end of intervention

Method of measurement

Fertility problem inventory

2

Description

Infertility adjustment

Timepoint

Before the intervention, at end of the intervention, and follow- up of 6 months after the end of intervention

Method of measurement

Infertility Adjustment Scale

Intervention groups

1

Description

Intervention group 1: The participants in this group receive computerized cognitive behavioral therapy 8 session during two month, 50 minutes, once a week.

Category

Treatment - Other

2

Description

Intervention group 2: Participants in this group receive individually face-to- face cognitive behavioral therapy, 8 sessions during two month 50 minutes, once a week.

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

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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Name of organization / entity

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Grant name

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
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Mahbobeh Faramarzi
Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more informatiom
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