

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Exploring the effect of cognitive - behavioral counseling on anxiety, depression, quality of life and marital satisfaction through virtual education

Protocol summary

Study aim

Determining the effect of cognitive-behavioral counseling on mental health of infertile women through virtual education

Design

An intervention of randomized controlled trials in two groups of controlled, double-blind, pre-test pre-test post-test research design.

Settings and conduct

After obtaining a license from Islamic Azad University, Falavarjan Branch, and providing a research environment and observing ethical considerations, the case group was enrolled in a study of 30 patients with a control group of 30 who were confirmed by infertility by a gynecologist. And consent will be obtained from them. When specifying the samples, they will be given personalized mobile phone numbers and educational materials through telegrams in a textual form as well as in vides. Anxiety, depression and quality of life will be measured before and after intervention.

Participants/Inclusion and exclusion criteria

Age 20-45 years old; being Muslim; Iranian nationality; having at least elementary education; not having a degree in psychology and counseling; lack of drug addiction; not having severe and well-known physical and mental illness.

Intervention groups

After obtaining a license from Islamic Azad University, Falavarjan Branch, and providing a research environment and observing ethical considerations, the case group was enrolled in a study of 30 patients with a control group of 30 who were confirmed by infertility by a gynecologist. And consent will be obtained from them. When specifying the samples, they will be given personalized mobile phone numbers and educational materials through telegrams in a textual form as well as in vides. Anxiety, depression and quality of life will be measured

before and after intervention

Main outcome variables

Anxiety; depression; quality of life and marital satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131110015349N3**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Maryam Allahdadian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1668 7140

Email address

allahdadian@iaufala.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring the effect of cognitive - behavioral counseling on anxiety, depression, quality of life and marital satisfaction through virtual education

Public title

Exploring the effect of cognitive - behavioral counseling on anxiety, depression, quality of life and marital satisfaction through virtual education

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 20-45 years old Being Muslim Nationality Iranian Having at least elementary education - Not having a degree in psychology and counseling No drug addiction Not having severe and well-known physical and mental illness

Exclusion criteria:

Unwillingness to participate in research Patients who used anti-depressant and anti-inflammatory drugs during the study

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People who go to the Infertility Center are being given one-on-one appointment

Blinding (investigator's opinion)

Single blinded

Blinding description

Contributors were kept blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University of Najaf Abad

Street address

Islamic Azad University of Najaf Abad, University Blvd.

City

Najaf Abad

Province

Isfahan

Postal code

8514143131

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1397.018

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2**Description of health condition studied**

Depression

ICD-10 code

F31.10

ICD-10 code description

Bipolar disorder, current episode manic without psychotic features, unspecified

3**Description of health condition studied**

Quality of Life

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Marital Satisfaction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Depression

Timepoint

Before and one month after the intervention

Method of measurement

questionnaire

2

Description

Quality of Life

Timepoint

Before and one month after the intervention

Method of measurement

questionnaire

3

Description

Marital Satisfaction

Timepoint

Before and one month after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study, after obtaining a license from Islamic Azad University, Falavarjan Branch, and presenting to the research environment and ethical considerations, the case group was enrolled in a study of 30 patients with a control group of 30 who confirmed their infertility by obstetrician. At the beginning of the work, for each sample, the title of the study and the method of work will be described and the consent form will be completed in the form of the consent form. When specifying samples, they are taken from their personal mobile phone number or email, and educational materials are provided via telegram or e-mail, as well as in plain text. Individual questions will also be answered by telegram or by message or telephone call. Anxiety, depression and quality of life will be measured before and after intervention. It should be noted that none of these women will use drugs due to depression and anxiety at the time of the research. In addition, patients will be contacted every 2 weeks during the study and will be assured of the lack of use of the medication

Category

Rehabilitation

2

Description

Control group: Control group: In this study, after obtaining permission from the Islamic Azad University of Falavarjan Branch and presenting to the research environment and observing ethical considerations, the case group was enrolled in a study of 30 patients with a control group of 30 who were afflicted with infertility by obstetrician and obstetrician. . At the beginning of the work, for each sample, the title of the study and the

method of work will be described and the consent form will be completed in the form of the consent form. When identifying the samples, depression anxiety, marital satisfaction and quality of life questionnaires are completed. Then, after completing one additional month, the questionnaires are completed again and the score for anxiety, depression and quality of life will be measured before and after each other. It should be noted that none of these women will use drugs due to depression and anxiety at the time of the research. Made In addition, patients will be contacted every 2 weeks during the study and will be assured of the lack of use of the medication. And in the event of a problem, due to ethical considerations, they were advised and excluded from intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecologist and infertility clinic

Full name of responsible person

Maryam Allahdadian

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University Blvd., Basij Boulevard,

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1558415

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maryamallahdadian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
maryam allahdadian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Maryam Allahdadin
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Other areas of specialty/work
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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

"No more information".

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

All people

Under which criteria data/document could be used

Use links with the sourc

From where data/document is obtainable

Researcher

What processes are involved for a request to access data/document

email

Comments