

# 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

##### **Street address**

University Blvd., Basij Boulevard,

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

1558415

##### **Phone**

+98 31 3742 0135

##### **Email**

maryamallahdadian@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Islamic Azad University

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

Maryam Allahdadian

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Islamic Azad University, University Blvd., Basij Boulevard, Falavarjan

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##### **Province**

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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**  
Midwifery  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Maryamallahdadian@yahoo.com

## 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**