Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 vises. 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 vises. 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)

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+98 31 1668 7140

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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 Abadad, University Blvd.
City
Najaf Abad
Province
Isfehan
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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Isfehan
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1558415
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Email
maryamallahdadian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Allahdadian
Street address
Islamic Azad University, University Blvd., Basij Boulevard, Falavarjan
City
Esfahan
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Phone
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Email
maryamallahdadian@yahoo.com

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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Position
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Allahdadin
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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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