Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of Cognitive-Behavioral Therapy on the Infertility Stress, Marital self regulation, Marital burnout and Intolerance of uncertainty on Infertile women.

Protocol summary

Study aim
Determining the effectiveness of cognitive-behavioral therapy on infertility stress, marital self-regulation, marital burnout and uncertainty intolerance in infertile women.

Design
A clinical trial with a control group, without a parallel group, non-random and targeted sampling, random assignment of members in the control and experimental groups, on 30 patients.

Settings and conduct
The treatment was done in the specialized obstetrics and gynecology clinic of Sari city, and the people diagnosed with infertility were selected non-randomly and randomly entered into the experimental and control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Receive a diagnosis of infertility Age between 20 and 40 years Not taking neuropsychiatric drugs in the last three months Absence of incurable psychiatric and physical illness They should be literate up to the fifth grade. Completion of the informed consent agreement regarding participation in the research project. Do not undergo treatment or other psychological interventions during the implementation of the research. Exclusion criteria: Absence of more than two sessions Use of psychoactive drugs or drugs during the last 5 months Having mania or a psychotic disorder Absence of entry criteria

Intervention groups
All four tests will be performed on the experimental and control groups (infertility stress, marital self-regulation, marital boredom, and uncertainty intolerance). The control group will not be intervened, but the experimental group will undergo 12 sessions of cognitive-behavioral therapy, then for both groups. The questionnaire will be re-administered. After 45 days after the post-test, the tests will be re-administered (follow-up period).

Main outcome variables
Reducing infertility stress, reducing marital boredom, increasing marital self-regulation, reducing uncertainty intolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230524058277N1**
Registration date: **2023-06-01, 1402/03/11**
Registration timing: **retrospective**

Last update: **2023-06-01, 1402/03/11**
Update count: **0**

Registration date
2023-06-01, 1402/03/11

Registrant information

Name
Bahram Mirzaian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-25, 1401/09/04

Expected recruitment end date
2022-12-10, 1401/09/19

Actual recruitment start date
2022-12-11, 1401/09/20
Actual recruitment end date
2022-12-16, 1401/09/25
Trial completion date
2023-05-05, 1402/02/15

Scientific title
Efficacy of Cognitive-Behavioral Therapy on the Infertility Stress, Marital self regulation, Marital burnout and Intolerance of uncertainty on Infertile women.

Public title
Efficacy of Cognitive-Behavioral Therapy on the Infertility Stress, Marital self regulation, Marital burnout and Intolerance of uncertainty on Infertile women.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1. Getting a diagnosis of infertility by a gynecologist. 2. Age between 20 and 40 years 3. Not taking neuropsychiatric drugs during the last three months 4. Do not suffer from an incurable physical disease such as cancer, MS, Alzheimer's and the like. 5. Do not have a serious psychiatric illness such as psychotic or similar. 6. They should be literate up to the fifth grade. 7. Completion of the consent letter regarding participation in the research project. 8. Do not undergo treatment or other psychological interventions during the implementation of the research
Exclusion criteria:
1. Getting a diagnosis of infertility by a gynecologist2. Age between 20 and 40 years3. Not taking neuropsychiatric drugs during the last three months4. Do not suffer from an incurable physical disease such as cancer, MS, Alzheimer's and the like.5. Do not have a serious psychiatric illness such as psychotic or similar.6. They should be literate up to the fifth grade.7. Completion of the consent letter regarding participation in the research project.8. Do not undergo treatment or other psychological interventions during the implementation of the research
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **15**
Actual sample size reached: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used

Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Islamic Azad University, Sari Branch
Street address
km 7 Darya road, Sari, Mazandaran province
City
Sari
Province
Mazandaran
Postal code
4816119318
Approval date
2023-02-14, 1401/11/25
Ethics committee reference number
IR.IAU.SARI.REC.1401.217

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
1. A decrease in the subject's score in the infertility stress questionnaire.
Timepoint
The first treatment session, the twelfth session and 45 days after the last treatment session.
Method of measurement
Infertility stress questionnaire4. Intolerance of uncertainty questionnaire

2

Description
2. A decrease in the subject's score in the Marital burnout questionnaire
Timepoint
The first treatment session, the twelfth session and 45 days after the last treatment session.

Method of measurement
2. Marital burnout questionnaire

3

Description
3. An increase in the subject's score in the Marital self-regulation questionnaire.
Timepoint
The first treatment session, the twelfth session and 45 days after the last treatment session.
Method of measurement
3. Marital self-regulation questionnaire.

4

Description
A decrease in the subject's score in the Intolerance of uncertainty questionnaire.
Timepoint
The first treatment session, the twelfth session and 45 days after the last treatment session.
Method of measurement
4. Reducing the subject's score in the Intolerance of uncertainty questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: cognitive-behavioral therapy is a type of psychotherapy that is a mixture of cognitive therapy and behavioral therapy techniques, this approach is based on the assumption that false thoughts and beliefs are the foundation of problematic emotions and behaviors, and based on this, it is not the incidents and events that They make the person uncomfortable, but the way of thinking that is the result of his beliefs, schemas and attitude, which affects the way of information processing and causes emotions and reactions, causes him discomfort. . Major emphasis on changing the irreconcilable and replacement cognitions It is taken into account. The main emphasis is on changing irreconcilable cognitions and replacing them with efficient cognitions. This structured, collaborative, time-limited therapy emphasizes the role of homework, and holds the therapist responsible for accepting an active role in therapy sessions and outside of it. and is focused on the present time, in this treatment, two cognitive strategies such as discovering cognitive distortions and disturbing thoughts, cognitive reconstruction and strengthening of fruitful counter-narratives, and behavioral strategies such as modeling, confronting, and acting out role, muscle relaxation, training coping skills and increasing Self-control and self-efficacy are used. The first session: conducting the pre-test, establishing a therapeutic relationship, explaining the rules and structure of the sessions, creating a preliminary agreement on the goals and expectations of the treatment, getting to know the basic principles of cognitive-behavioral therapy, presenting homework. The second session: Getting to know the cognitive model-behavior includes identifying the chain of cognitive-behavioral events, presenting homework. The third session: reviewing assignments, recognizing situations, feelings, opinions and thoughts and specific actions (behavior), presenting homework. Fourth session: reviewing assignments, antecedents and consequences of behavior, situation Motivating, methods of reducing anxiety, presentation of homework. Fifth session: review of homework, identification of negative spontaneous thoughts, cognitive errors (especially regarding infertility), presentation of homework.The sixth session: review of assignments, training in visualization and diaphragmatic breathing and training in gradual muscle relaxation, presentation of homework. Seventh session: review of assignments, training in examining the evidence of thoughts (especially about thoughts related to infertility), training in examining the benefits and harms of thoughts (especially regarding thoughts related to infertility), presentation of homework. Eighth session: review of homework, training to control thoughts, emotions and behavior related to emotions, presentation of homework. Ninth session: review of homework, classification of techniques related to anxiety, training in ways to deal with Anxiety and intolerance of uncertainty, presentation of homework. Tenth session: reviewing assignments, teaching effective communication and discussing its effects. Creating the skill of transmitting and receiving clear, correct and effective thoughts, feelings and needs, especially in the marital relationship, presentation of homework. The 11th session: reviewing assignments, reviewing the assignments of the previous session, teaching problem-solving methods, especially regarding the problem of infertility and related issues such as the treatment process, teaching planning for health-promoting behaviors such as following a healthy diet, stress management, engaging in activities physical, presenting homework. twelfth session: reviewing homework, summarizing sessions, summarizing materials, receiving feedback from the client, appreciation and gratitude, post-exam implementation.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized gynecology, maternity and infertility clinic of Dr. Niaz Nikkhah
Full name of responsible person
Niaz Nikkhah
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Unit 43, 4th floor, Nagin Complex, Sarkoi Seng, Taleghani Blvd., Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Sari
Full name of responsible person
Ali Abbaszadeh Suri
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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 of Sari
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 of Sari
Full name of responsible person
Fatemeh Talebi
Position
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Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts one month after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions and gynecology and obstetrics and infertility doctors

Under which criteria data/document could be used

There are no special conditions for access.

From where data/document is obtainable

Be in touch with the email address provided. yeganeh_talebi_1998@yahoo.com

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

After sending the request for obtaining the documents to the e-mail, the documents will be sent after 10 working days.

Comments