

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 11 3325 9528

##### **Email address**

bahrammirzaian@gmail.com

##### **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 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

**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 questionnaire 4. 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

##### Street address

Unit 43, 4th floor, Nagin Complex, Sarkoi Seng, Taleghani Blvd., Sari

##### City

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**Email**

dr.niaznikkhah@yahoo.com

**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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Mazandaran Province, Farah Abad Road,

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ravabet-omomi@iau-tnb.ac.ir

**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**

MSc in Clinical Psychology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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Hasanpour Alley, Moalem St., Sari, Mazandaran

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Bahram Mirzaian

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University of Sari

**Full name of responsible person**

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**Position**

MSc in Clinical Psychology

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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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**