

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### The effectiveness of cognitive behavioral therapy (based on body image) on the general health of infertile women

#### Protocol summary

##### Study aim

The purpose of this study is to determine the effectiveness of cognitive-behavioral counseling based on body image on the general health of infertile women.

##### Design

No intervention is performed on the control group and they are placed on the waiting list.

##### Settings and conduct

24 qualified people will be selected and will be randomly assigned to one of two intervention and control groups. For the intervention group, 8 one-hour sessions per week for cognitive-behavioral counseling will be conducted by infertility research and treatment center of ACECR in Ahvaz. In this research, from the eight-step treatment to the weight-loss copper, which has eight steps to change the negative body image of people, and in each step, approved cognitive-behavioral methods are used to improve this body image.

##### Participants/Inclusion and exclusion criteria

Age 18-45 years- Cycle education-Having a history of infertility for at least two years-Diagnosing disorders in public health based on questionnaires;A woman getting pregnant - missing more than two sessions - mental problems

##### Intervention groups

The intervention group receives eight sessions of cognitive behavioral therapy. The duration of each session is 60 minutes and has a specific structure.No intervention is performed on the control group and they are placed on the waiting list.

##### Main outcome variables

Depression-anxiety-social functioning-physical symptoms-physical satisfaction

#### General information

##### Reason for update

##### Acronym

CBT

#### IRCT registration information

IRCT registration number: **IRCT20220713055457N5**

Registration date: **2023-06-23, 1402/04/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-23, 1402/04/02**

Update count: **0**

##### Registration date

2023-06-23, 1402/04/02

#### Registrant information

##### Name

Zohreh Ahmady

##### Name of organization / entity

Islamic Azad University Behbahan Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 916 982 5673

##### Email address

zohreh.ahmady@iau.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2023-06-16, 1402/03/26

##### Expected recruitment end date

2023-06-30, 1402/04/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The effectiveness of cognitive behavioral therapy (based on body image) on the general health of infertile women

**Public title**

The effectiveness of cognitive behavioral therapy (based on body image) on the general health of infertile women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18-45 years Cycle education Having a history of infertility for at least two years Diagnosing disorders in public health based on questionnaires

**Exclusion criteria:****Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method was simple random assignment. The randomization unit was the individual. A random sequence was created through a web-based numeric sequencer (<http://www.randomizer.org>). In order to hide the random allocation, the person involved in the randomization process was separate from other researchers to reduce possible bias.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Islamic Azad University  
Behbahan Branch

**Street address**

بهبهان، بلوار امیر کبیر، خیابان شهید بیانی

**City**

Behbahan

**Province**

Khuzestan

**Postal code**

6361713198

**Approval date**

2023-06-02, 1402/03/12

**Ethics committee reference number**

IR.IAU.BEHBAHAN.REC.1402.001

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

general health

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

General Health

**Timepoint**

Before the intervention - immediately after the intervention - one month after the intervention

**Method of measurement**

General health questionnaire(GHQ)

**2****Description**

Mental image of the body

**Timepoint**

Before the intervention - immediately after the intervention - one month after the intervention

**Method of measurement**

multidimensional body-self relationships  
Questionnaire(MBSRQ)

**Secondary outcomes****1****Description**

depression

**Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

**Method of measurement**

General health questionnaire(GHQ)

**2****Description**

anxiety

**Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

**Method of measurement**

General health questionnaire(GHQ)

**3****Description**

Social function

**Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

#### **Method of measurement**

General health questionnaire(GHQ)

#### **4**

##### **Description**

physical symptoms

##### **Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

##### **Method of measurement**

General health questionnaire(GHQ)

#### **5**

##### **Description**

physical satisfaction

##### **Timepoint**

Before the intervention, immediately after the intervention, one month after the intervention

##### **Method of measurement**

General health questionnaire(GHQ)

## **Intervention groups**

#### **1**

##### **Description**

Intervention group: The intervention group receives 8 sessions of cognitive behavioral therapy based on body image. The duration of each session is 60 minutes and has a specific structur.

##### **Category**

Behavior

## **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Infertility research and treatment center of ACECR  
Khuzestan

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

Zohreh Ahmady

###### **Street address**

Pardis St., Gladis Blvd.,

###### **City**

Ahvaz

###### **Province**

Khuzestan

###### **Postal code**

8656435766

###### **Phone**

+98 916 982 5673

###### **Email**

info@ahz-ivf.ir

## **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

Islamic Azad University

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

shahroei

###### **Street address**

Shahid Bayani Ave.,AmirKabir Blvd.,Behbahan City

###### **City**

Behbahan

###### **Province**

Khuzestan

###### **Postal code**

6361713198

###### **Phone**

+98 61 5287 0105

###### **Fax**

###### **Email**

info@behu.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

No

##### **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**

Zohreh Ahmady

###### **Position**

Instructor

###### **Latest degree**

Master

###### **Other areas of specialty/work**

Midwifery

###### **Street address**

No25,Sepah1 Ave,Chahar shir Blvd,Ahvaz

###### **City**

Ahvaz

###### **Province**

Khuzestan

###### **Postal code**

6165664573

**Phone**

+98 916 982 5673

**Email**

Zohreh.Ahmady@iau.ac.ir

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

Islamic Azad University

**Full name of responsible person**

Zohreh Ahmady

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

No25, Sepah1 Ave, Chahar shir Blvd, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6165664573

**Phone**

+98 916 982 5673

**Email**

Zohreh.Ahmady@iau.ac.ir

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

Islamic Azad University

**Full name of responsible person**

Zohreh Ahmady

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

No25, Sepah1 Ave, Chahar shir Blvd, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6165664573

**Phone**

+98 916 982 5673

**Email**

Zohreh.Ahmady@iau.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available