Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 Univercity Behbahan Branch
Country
Iran (Islamic Republic of)
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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
Khouzestan
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 Khouzestan

Full name of responsible person

Zohreh Ahmady

Street address

Pardis St., Gladis Blvd.,

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8656435766

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

shahrooei

Street address

Shahid Bayani Ave.,AmirKabir Blvd.,Behbahan City

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Behbahan

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Fax

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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

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No25,Sepah1 Ave,Chahar shir Blvd,Ahvaz

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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