Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The Effectiveness of Cognitive Behavioral treatment on Body Image in Infertile Women.

Protocol summary

Summary

The purpose of this study is to recognize the effectiveness of cognitive-behavioral treatment on body image in infertile women. This study, as a clinical design, is carried on 24 infertile women afflicted with negative body image. Inclusion criteria are: age (18-45 years), at least two years afflicted with infertility, reorganization of woman infertility, the ability to read and write, concerns about negative body image based on the questionnaire, normal BMI, and primary infertility. And exclusion criteria are: pregnancy, being absent for more than 2 sessions, and psychological problems. Data are analyzed using questionnaire of multidimensional body self relation, questionnaire of concern about body image (BICI), and questionnaire of Beck self-concept. As the necessary score is obtained through questionnaires, women are divided randomly into two experimental and control groups (12 in each group). The intervention group receives 8 weeks 1-hour sessions for cognitive-behavioral counseling conducted by researcher. After the end of consultation and one month later, both groups reassess using questionnaire of multidimensional body self relation and questionnaire of concern about body image. The primary outcome of this study is to improve the body image in infertile women in experimental group based on questionnaires' score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100529877N1**
Registration date: **2016-10-05, 1395/07/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-05, 1395/07/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-10-11, 1395/07/20

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Cognitive Behavioral treatment on Body Image in Infertile Women.

Public title

The Effects of Cognitive Behavior therapy on Body Image

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: age (18-45 years); at least two years afflicted with infertility; reorganization of woman

infertility; the ability to read and write; concerns about negative body image based on the questionnaire; normal BMI; and primary infertility. exclusion criteria are: pregnancy; being absent for more than 2 sessions; psychological problems.

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

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 Ahvaz Jundishapur University of Medical Sciences

Street address
Ground Floor, Department of Research and Information Technology University of Medical Sciences, Ahvaz Jundishapour.

City
Ahvaz

Postal code

Approval date
2016-07-19, 1395/04/29

Ethics committee reference number
1395.262

Health conditions studied

1

Description of health condition studied
Body Image

ICD-10 code
F45.2

ICD-10 code description
Body Dysmorphic Disorder

Primary outcomes

1

Description
Body Image

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Mbsrq, Beck Self-Concept And Bici Questionnaries

2

Description
Body Image Concerns

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Bici Test

Secondary outcomes

1

Description
Body areas satisfaction

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Multidimensional Body-Self Relations Questionnaire

2

Description
Fitness orientation

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Multidimensional Body-Self Relations Questionnaire

3

Description
Fitness evaluation

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Multidimensional Body-Self Relations Questionnaire

4

Description
Appearance evaluation

Timepoint
Before the intervention, immediately after intervention, a month after the intervention.

Method of measurement
Multidimensional Body-Self Relations Questionnaire

Intervention groups

1

Description
The intervention group received eight sessions of cognitive behavioral therapy. Each session is 60 minutes long and has a specific structure.
Category
Behavior

2

Description
They had no treatment and were in waiting list.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Research and Treatment Center Of ACECR Khoozestan
Full name of responsible person
Zohreh Ahmady
Street address
Khuzestan Province, Ahvaz, Pardis Blv.
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Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
Full name of responsible person
Dr Behzad Sharief Makhmal
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Ground Floor, Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty