

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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

Name

Zohreh Ahmady

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 4322 8961

Email address

ahmadi.z@ajums.ac.ir

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 Jundishapur.

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 Questionnaires

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.

City

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

Street address

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

Contact

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences,
Ahvaz, Iran

Full name of responsible person

Zohreh Ahmady

Position

Master Student of consultation in Midwifery

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences,
College of Nursing and Midwifery

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

zohrehahmady2@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences,
Ahvaz,Iran

Full name of responsible person

Zahra Abbaspoor

Position

Phd of Reproductive Health

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences,
College of Nursing and Midwifery

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

Abbaspoor_z762@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

Full name of responsible person

Zohreh Ahmady

Position

Master Student of Consultation in Midwifery

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences,
College of Nursing and Midwifery

City

Ahvaz

Postal code

Phone

+98 61 3336 7543

Fax

Email

zohrehahmady2@gmail.com

Web page address

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