

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of Cognitive Behavioral Therapy on Psychological Well-being in Infertile Women

Protocol summary

Study aim

The purpose of this study was to investigate the effect of cognitive-behavioral counseling on psychological well-being of infertile women

Design

This is an interventional study with control group and random allocation that is performed on 68 infertile women with low psychological well-being

Settings and conduct

Infertility Clinic is the Imam Khomeini Hospital of Ahvaz. The data were analyzed using Riff's Psychological Well-Being Questionnaire and the available sampling and allocation of people in each of the two groups were randomly assigned to the test and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1. Has primary infertility 2- Ability to read and write 3. Infertile women aged 20 to 45 years 4. The desire to attend group therapy sessions and participate in the study 5. Obtain a psychological well-being score, a standard deviation below the average
Exclusion criteria include: 1. Severe psychological illness during the study 2. More than two absences from counseling sessions 3- Pregnancy 4. Having an adopted child

Intervention groups

For the intervention group, cognitive-behavioral counseling will be done by the researcher in the form of 8 120-minute sessions per week. After the end of the consultation period, one month later, both groups were re-evaluated with the Reef Psychological Well-being Questionnaire.

Main outcome variables

The primary outcome is psychological well-being in infertile women of the intervention group according to the score of the questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043019N1**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **prospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Zahra Marashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3444 3844

Email address

marashi.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive Behavioral Therapy on Psychological Well-being in Infertile Women

Public title

The Effect of Cognitive Behavioral Therapy on Psychological Well-being

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria:1. Has primary infertility 2- Ability to read and write 3. Infertile women aged 20 to 45 years 4. The desire to attend group therapy sessions and participate in the study 5. Obtain a psychological well-being score, a standard deviation below the average

Exclusion criteria:

Exclusion criteria:1. Severe psychological illness during the study 2. More than two absences from counseling sessions 3- Pregnancy 4. Having an adopted child

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

68 Infertile women referred to Imam Khomeini Hospital's Infertility clinic in Ahvaz who are eligible to enter the study randomly divided by draw cards in intervention and control groups so that the number of subjects in the two groups is equal.

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 Universi

Street address

Ahvaz, Deputy of Research and Technology,
Jundishapur University of Medical Sciences and Health
Services, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.AJUMS.REC.1397.931

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

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Psychology well being

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

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

Self acceptance

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

2**Description**

Positive relationship with others

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

3**Description**

Autonomy

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

4

Description

Environmental domination

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

5

Description

Goal in life

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

6

Description

Personal growth

Timepoint

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

Method of measurement

Ryff psychological well-being questionnaire

Intervention groups

1

Description

Intervention group: The intervention group receives eight sessions of cognitive-behavioral therapy. The duration of each session is 120 minutes and has a specific structure

Category

Behavior

2

Description

Control group: There was no intervention on the control group and they were placed on the waiting list

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Ahvaz Imam Khomeini Hospital

Full name of responsible person

Zahra Marashi

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Azadegan

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AMAMKHOMEINI-HOSPITAL@YAHOO.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badvi

Street address

Ahvaz, Dept. of Research and Information Technology, Ahwaz Jundishapur University of Medical Sciences and Health Services

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Marashi

Position

MS.c Student in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Zahra Abbaspoor

Position

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Ph.D.

Other areas of specialty/work

Reproductive Health

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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

After identifying the participants, the information will be shared with the original outcome

When the data will become available and for how long

The publication of the information will be possible six months after the publication of the results

To whom data/document is available

Access to research documentation for research centers and researchers and therapists is possible

Under which criteria data/document could be used

Approve Ahvaz University of Medical Sciences, Appropriateness of Information Required with Health Promotion Programs

From where data/document is obtainable

Ahvaz University of Medical Sciences, Vice-Chancellor of Research and Technology, Dr. Mohammad Badvi, Postal code 61357-15794 Phone 0098613311 Email info@ajums.ac.ir

What processes are involved for a request to access data/document

Following the correspondence with the research deputy of Ahvaz University of Medical Sciences, the results will be available to applicants.

Comments