Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 61 3444 3844

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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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6193673111
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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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info@ajums.ac.ir
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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Golestan University of Medical Sciences, Faculty of Nursing and Midwifery

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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)
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