

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effectiveness of cognitive-behavioral training on emotional dyslexia and distress tolerance in infertile women undergoing treatment

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral training on emotional dyslexia and distress tolerance in infertile women undergoing treatment in Ahvaz.

Design

As a cluster method, among the 4 infertility centers in the city, 2 centers were randomly selected, and among the infertile women under treatment, those who met the criteria for entering the study were selected in the desired number (70).

Settings and conduct

In the first step, the pre-test was performed, and then in the second step, the training protocol (9 training sessions) was performed for the experimental group, but no training was provided for the control group. In the third step, immediately after the completion of the last training session (ninth session), after the implementation test, the findings and data obtained from this research were analyzed and the researcher finally discussed and concluded.

Participants/Inclusion and exclusion criteria

Criteria for entering the research: 1- Willingness to cooperate and participate in research (satisfaction to participate in research) 2- The patient has been treated with intrauterine insemination (IUI) at least once 3- Infertility confirmed by a doctor 4- Vigilance and awareness of the disease 5_ Proficiency in Persian language 6- Lack of simultaneous attendance in cognitive-behavioral educational programs 7_ The ability to communicate 8_ Being treated by the patient
Exclusion criteria from the research: 1- Non-cooperation and not doing the homework of each meeting 2- Unwillingness to continue participating in research 3- Taking interventional drugs 4- Incomplete completion of the questionnaire 5_ Pregnancy 6_ Physical diseases 7- Over 40 years old

Intervention groups

Subjects were randomly assigned to two experimental and control groups of 35 people in each group

Main outcome variables

Cognitive behavioral training, emotional dyslexia and distress tolerance

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20240112060692N1**

Registration date: **2024-01-18, 1402/10/28**

Registration timing: **retrospective**

Last update: **2024-01-18, 1402/10/28**

Update count: **0**

Registration date

2024-01-18, 1402/10/28

Registrant information

Name

Kosar Pourdastan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3553 4457

Email address

kosarpour0@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-15, 1402/02/25

Expected recruitment end date

2023-05-23, 1402/03/02

Actual recruitment start date

2023-05-15, 1402/02/25

Actual recruitment end date

2023-05-25, 1402/03/04

Trial completion date

2023-07-21, 1402/04/30

Scientific title

The effectiveness of cognitive-behavioral training on emotional dyslexia and distress tolerance in infertile women undergoing treatment

Public title

The effectiveness of cognitive-behavioral training on emotional dyslexia and distress tolerance in infertile women undergoing treatment

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to cooperate and participate in research (satisfaction to participate in research) The patient has been treated with intrauterine insemination (IUI) at least once Infertility disease confirmed by a doctor Awareness and awareness of the disease Proficiency in Persian language Lack of simultaneous attendance in cognitive-behavioral educational programs Ability to communicate The patient is being treated

Exclusion criteria:

Non-cooperation and not doing the homework of each session Unwillingness to continue participating in research Use of interventional drugs Incomplete completion of the questionnaire pregnancy physical diseases Over 40 years old

AgeFrom **20 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70**Actual sample size reached: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to carry out the research, the infertility centers of Ahvaz city were referred to and 2 centers were randomly selected from among the 4 infertility centers in the city, and among the infertile women under treatment, there were people who met the entry criteria for the research. 70 people were selected. The working method was that the subjects were randomly placed in two test groups and 35 people in each control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University, Kazeroon branch

Street address

No. 73, 9 West Street, Padadshahr

City

Ahvaz

Province

Khouzestan

Postal code

618395191

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.IAU.KAU.REC.1402.045

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

Cognitive-behavioral training on emotional dyslexia and distress tolerance

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of cognitive-behavioral training on ataxia in the Toronto ataxia questionnaire and distress tolerance in Simmons and Gaher's distress tolerance questionnaire.

Timepoint

Before starting the cognitive-behavioral training, ataxia was 22.57 and distress tolerance was 48.09, and after the intervention, ataxia decreased to 48.03 and distress tolerance increased to 34.53.

Method of measurement

Alexithymia was measured with the Toronto Alexithymia Questionnaire and Distress Tolerance was measured with the Simmons and Gaher Distress Tolerance Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: At first, a pre-test was taken from the group, and then the cognitive-behavioral training protocol was taught to 35 subjects in 9 sessions of 60-90 minutes, and at the end of the last session, a post-test was taken from the subjects.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Department of Imam Khomeini Hospital

Full name of responsible person

Kosar Pourdastan

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No. 73, Padadshahr West 9th Street, Moheb Building, Unit 2

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6183895191

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kosarpour0@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal budget

Full name of responsible person

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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

0

Proportion provided by this source

1

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University, Shiraz branch

Full name of responsible person

kosar pourdastan

Position

psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ali Nasery

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Assistant Professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Graduated from Islamic Azad University

Latest degree

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Other areas of specialty/work

Psychology

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Fax**Email**

kosarpour0@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the subjects' information and maintaining the condition of confidentiality, we are not allowed to publish the participants' information

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is no permission to publish the information of the clients

When the data will become available and for how long

never

To whom data/document is available

The person responsible for the research

Under which criteria data/document could be used

Due to the principle of confidentiality, it is not possible at all

From where data/document is obtainable

Send an email to the person responsible for the research
kosarpour0@gmail.com

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

Send an email to the person responsible for the research
kosarpour0@gmail.com

Comments