

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

Comparing the Effectiveness of Cognitive Behavioural Therapy in Individual and Couple Settings on Negative Emotional States, Fertility Problem and Pregnancy Rate in Infertile Women

Protocol summary

Study aim

This trial aims to compare the effectiveness of two methods of delivering cognitive behavioral therapy (individual and couples) on negative emotional states, fertility problem, and pregnancy rate in infertile women seeking assisted reproductive treatment.

Design

A controlled clinical trial with parallel groups, single-blind, randomized, on 100 participants, using the website <http://www.Randomization.com> for randomization.

Settings and conduct

The intervention will be conducted at the Milad Infertility Clinic located at Imam Reza Hospital in Mashhad. Clients who complete an informed consent form will be randomly assigned to one of three groups, with the experimental group receiving a course of cognitive behavioral therapy, either individually or in pairs, delivered by a trained therapist. The control group does not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Couples who are candidates for In vitro fertilization(IVF) or Intracytoplasmic sperm injection(ICSi). Age less than 40 years Must have at least a middle school education. Not taking psychiatric medications No history of suicide The couple's karyotype should be normal. The criteria for not entering the trial are also receiving other psychological treatment at the same time, not being physically or mentally fit enough to answer the questionnaires or attend the meetings.

Intervention groups

This clinical trial consists of two experimental groups and a control group. The experimental groups receive a course of cognitive behavioral therapy individually or in pairs, and The control group does not receive any intervention.

Main outcome variables

Negative emotional states, fertility problems, pregnancy

rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241117063755N1**

Registration date: **2024-12-16, 1403/09/26**

Registration timing: **prospective**

Last update: **2024-12-16, 1403/09/26**

Update count: **0**

Registration date

2024-12-16, 1403/09/26

Registrant information

Name

Maryam Sedaghat

Name of organization / entity

Shahid Bahonar University of Kerman

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-18, 1403/10/29

Expected recruitment end date

2025-07-20, 1404/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the Effectiveness of Cognitive Behavioural Therapy in Individual and Couple Settings on Negative Emotional States, Fertility Problem and Pregnancy Rate in Infertile Women

Public title
Comparing the Effectiveness of Individual Cognitive Behavioural Therapy and Couple Cognitive Behavioural Therapy on Negative Emotional States, Fertility Problem and Pregnancy Rate in Infertile Women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Be under 40 years of age. Follicle-stimulating hormone is less than 10. Body mass index is less than 30. Must have at least a middle school education. Not taking psychiatric medications No history of suicide The patient does not have Uterine abnormalities or thrombophilia. The couple's karyotype should be normal. There is no strong male factor in infertility. Couples who are candidates for in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI).
Exclusion criteria:
Receiving other psychological treatment at the same time Not being physically or mentally fit to answer questionnaires or attend meetings

Age
To **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who meet the criteria for entering the project and have filled out the informed consent form will be randomly placed into three groups (experimental group one (individual CBT), experimental group two (couple CBT), and control group). It should be noted that the web-based randomization method and the site <http://www.Randomization.com> are used to randomly assign individuals to groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The researcher and clinical caregiver are not blinded to the experiment, but the person analyzing the data is blinded to the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

No: Ebn Sina Ave., Jihad Blvd., Kerman., Iran

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Postal code

7616913555

Approval date

2024-11-26, 1403/09/06

Ethics committee reference number

IR.KMU.REC.1403.372

Health conditions studied

1

Description of health condition studied

Depression, stress, anxiety, infertility-related stress

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

Primary outcomes

1

Description

Depression, anxiety, and stress scores in the Depression Anxiety Stress Scalls-21

Timepoint

Measurement of Negative Emotional States before the start of the intervention and 60 days later (immediately after the end of the intervention)

Method of measurement

Depression Anxiety Stress Scalls-21

2

Description

Infertility-related stress score on the Fertility Problem Questionnaire

Timepoint

Measurement of infertility-related stress before the intervention began and 60 days later (immediately after

the intervention ended)
Method of measurement
Fertility Problem Questionnaire

Secondary outcomes

1

Description

chemical Pregnancy

Timepoint

Two weeks after assisted reproductive treatment or one month after completing cognitive behavioral therapy

Method of measurement

Gonadotropin hormone measurement through blood test

Intervention groups

1

Description

First intervention group: Individual cognitive behavioral therapy. This psychological therapy is provided in 10 sessions and its components include identifying and correcting cognitive biases and ineffective emotion regulation strategies.

Category

Behavior

2

Description

Second intervention group: Cognitive behavioral couple therapy. This psychological therapy is provided in 10 sessions and its components include training in communication skills, problem solving, expressing emotions, cognitive restructuring, tolerance, and acceptance.

Category

Behavior

3

Description

Control group: This group does not receive any intervention and is placed on a waiting list.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Clinic, Imam Reza Hospital

Full name of responsible person

Seyede Maryam Sedaghat

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NO. Ebne Sina St., Mashhad., Razavi Khorasan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shahid Bahonar University of Kerman

Full name of responsible person

Alireza Saidi

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Vice Chancellor for Research and Technology., Shahid Bahonar University., Pazhohesh Sq., Imam Khomeini Hwy., Kerman

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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
Shahid Bahonar University of Kerman

Proportion provided by this source
50

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
Shahid Bahonar University of Kerman

Full name of responsible person
Maryam Sedaghat

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available