

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

The effectiveness of cognitive-behavioral counseling based on the "interactive cognitive subsystems" approach on anxiety, depression, and feelings of shame and guilt

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral counseling based on the "interactive cognitive subsystems" approach on anxiety, depression, and feelings of shame and guilt in infertile couples referring to psychological centers in Ahvaz

Design

A controlled clinical trial with parallel groups, single-blind, randomized, on 30 pairs. Random Allocation Software was used for randomization.

Settings and conduct

The study will be conducted at psychological centers in Ahvaz. Infertile couples will be selected after screening based on inclusion criteria. Random allocation to groups will be performed by an independent research assistant. Cognitive-behavioral intervention based on the interacting cognitive subsystems approach will be delivered. Outcome assessors and data analysts will remain blinded. Data collection will be carried out using standardized questionnaires before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile couples aged 25-45 years. Diagnosis of infertility by a gynecologist. Presence of measurable anxiety or depression symptoms. Informed consent and willingness of both spouses. Exclusion criteria: History of severe psychiatric disorders. Current use of psychiatric medications. Concurrent receipt of any psychotherapy. Unwillingness of either spouse to continue participation.

Intervention groups

The intervention group consists of infertile couples who receive cognitive-behavioral counseling sessions based on the "interactive cognitive subsystems" approach. The goal of these sessions is to reduce their anxiety, depression, and feelings of shame and guilt. The control group consists of infertile couples who receive no

intervention and are simply under routine clinical supervision.

Main outcome variables

Anxiety, Depression, Shame, Guilt.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250704066367N1**

Registration date: **2025-09-14, 1404/06/23**

Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**

Update count: **0**

Registration date

2025-09-14, 1404/06/23

Registrant information

Name

Syedah Zahra Tabatabayi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3111 1111

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-01, 1404/07/09

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of cognitive-behavioral counseling based on the "interactive cognitive subsystems" approach on anxiety, depression, and feelings of shame and guilt

Public title
The impact of cognitive-behavioral approach on anxiety, depression, and feelings of shame and guilt.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age criterion of 25-45 years for both spouses. Diagnosis of infertility by a gynecologist. Presence of measurable anxiety or depression. Informed consent and willingness of both spouses.
Exclusion criteria:
 History of severe psychiatric disorder. Current use of psychiatric medications. Concurrent receipt of psychotherapy. Unwillingness of one spouse to participate.

Age
From **25 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method used in this study is block randomization with a block size of 4. The allocation sequence will be generated using Random Allocation Software and placed in consecutive sealed envelopes. After final confirmation of each participant's entry conditions, the researcher will open the envelopes in order to allocate individuals to the intervention or control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study will be designed as a single-blind study. In this design, only the outcome assessors and data analysts will be kept unaware of the allocation of couples to the intervention and control groups. This will ensure that data collection and analysis of the results are free from any bias. Participating couples will be fully aware of the nature of the study and their treatment group, as this information will be provided transparently

during the informed consent process. The principal investigator and treatment personnel will also be informed of the details of group allocation to enable safe and effective delivery of the interventions. This approach will ensure that data integrity and impartiality in the assessment of the results are maintained.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Ahvaz Branch

Street address

Islamic Azad University Ahvaz Branch, Farhangshahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

3733361349

Approval date

2025-08-30, 1404/06/08

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.412

Health conditions studied

1

Description of health condition studied

Feelings of shame and guilt

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fertility-Related Quality of Life Index (FERIS)

Timepoint

At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement

Fertility-Related Quality of Life Questionnaire (Ferticol, 2011)

Secondary outcomes

1

Description

Depression

Timepoint

At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement

Beck Depression Inventory-II

2

Description

Feelings of shame and guilt

Timepoint

At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement

Orth Shame and Guilt Scale Questionnaire

3

Description

Anxiety,

Timepoint

At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement

Beck Anxiety Inventory (BAI)

Intervention groups

1

Description

Intervention group: Intervention group (infertile couples): This group will receive a cognitive-behavioral counseling protocol based on the interacting cognitive subsystems approach. The intervention will consist of 12 structured 90-minute sessions conducted weekly. Session content will include identifying and modifying maladaptive thought patterns, managing negative emotions, and improving marital communication related to infertility.

Category

N/A

2

Description

Control group: Control group (infertile couples): This group will receive no psychological intervention and will only be placed on a waiting list. Pre- and post-test assessments using standardized questionnaires will be conducted for this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ahvaz Unit

Full name of responsible person

Siyed Kazam Mousavi

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Islamic Azad University Ahvaz Branch, Farhangshahr, Golestan Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Siyed Kazam Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Family Counseling

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Person responsible for scientific inquiries

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Name of organization / entity

Islamic Azad University

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Siyed Kazam Mousavi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Syedeh Zahra Tabatabayi

Position

Student

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Bachelor

Other areas of specialty/work

Consulting

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable