

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effectiveness of acceptance and commitment therapy on quality of life, marital adjustment, and marital commitment of infertile couples.

Protocol summary

Study aim

The overall goal is to determine whether implementing ACT sessions can help reduce psychological distress caused by infertility and promote relationship health in infertile couples.

Design

A controlled clinical trial with parallel groups, unblinded, randomized, on 30 couples. The rand function of Excel software was used for randomization.

Settings and conduct

This study is conducted as a randomized clinical trial in psychological centers in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being a Married Couple with at Least One Year of Cohabitation, Confirmed Diagnosis of Infertility by a Gynecologist or Urologist, Participants Aged Between 20 and 45 Years, Presence of Marital Conflict or Decreased Quality of Life Related to Infertility, Written Consent and Willingness of Both Partners to Participate in the Sessions. Exclusion Criteria: Severe Psychiatric Disorders (Such as Schizophrenia, Bipolar I Disorder, or Borderline Personality Disorder), Ongoing Legal Disputes, Divorce Proceedings, or Living Separately, Active Addiction or Substance Abuse, History of Severe Domestic Violence or Spousal Abuse

Intervention groups

Intervention group: Includes infertile couples who participate in Acceptance and Commitment Therapy (ACT) sessions. This intervention is held in the form of 8 to 10 90-minute sessions, couple-centered and in-person at psychological centers in Ahvaz. The content of the sessions includes emotional acceptance skills, mindfulness, value clarification, and committed action to improve the quality of life and marital relationship.

Main outcome variables

Quality of life, marital adjustment, marital commitment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250703066345N1**

Registration date: **2025-09-07, 1404/06/16**

Registration timing: **prospective**

Last update: **2025-09-07, 1404/06/16**

Update count: **0**

Registration date

2025-09-07, 1404/06/16

Registrant information

Name

Abdollah jnamy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3682 0253

Email address

abdollahjnamy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-19, 1404/06/28

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of acceptance and commitment therapy on quality of life, marital adjustment, and marital commitment of infertile couples.

Public title

The effectiveness of acceptance and commitment therapy on quality of life, marital adjustment, and marital commitment of infertile couples.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being a couple and officially living together Infertility diagnosis Having conflict or reduced quality of life related to infertility Written consent and willingness of both couples to participate in the sessions Age range 20 to 45

Exclusion criteria:

Having severe psychiatric disorders Active addiction or substance abuse Experiencing severe marital violence or spousal abuse

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be performed using simple randomization with the "couple" as the unit. The allocation sequence will be generated using a standard random number table, and sequentially numbered, sealed, opaque envelopes will be used to ensure allocation concealment. After confirming the eligibility of each couple, the corresponding envelope will be opened by an independent researcher according to the order of enrollment, and the group assignment (intervention or control) will be determined based on the pre-specified number inside the envelope. This procedure will prevent any bias in the allocation of participants.

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 Islamic Azad University, Ahvaz Branch

Street address

Islamic Azad University Ahvaz Branch, Farhangshahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

3733361349

Approval date

2025-06-12, 1404/03/22

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.166

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Quality of Life

Timepoint

At the beginning of the study, pre-test, before the start of the intervention, post-test, then immediately after the end of the treatment sessions.

Method of measurement

(RDAS) مقیاس کیفیت زناشویی باسبی و همکاران

Secondary outcomes

1

Description

Marital compatibility

Timepoint

At the beginning of the study, pre-test, before the start of the intervention, post-test, then immediately after the end of the treatment sessions.

Method of measurement

Spanier Marital Adjustment Questionnaire (1976)

Intervention groups

1

Description

Intervention group: Infertile couples participating in Acceptance and Commitment Therapy (ACT) sessions; consisting of 8 to 10 in-person couple-centered sessions aimed at improving quality of life and marital relationship

Category

N/A

2

Description

Control group: Infertile couples who do not receive any treatment intervention and only participate in the pre-test and post-test; this group is used for comparison with the intervention group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ahvaz Unit

Full name of responsible person

Shams Sobhani Joo

Street address

Islamic Azad University Ahvaz Branch, Farhangshahr, Golestan Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shams Sobhani Joo

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Family counseling

Street address

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Person responsible for scientific inquiries

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Shams Sobhani Joo

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Other areas of specialty/work

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Person responsible for updating data

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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