Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
مقیاس کیفیت زناشویی باسبی و همکاران (RDAS)

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
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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
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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
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Person responsible for scientific inquiries

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Shams Sobhani Joo
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Latest degree
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Other areas of specialty/work

Family counseling

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Person responsible for updating data

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Student

Latest degree
Bachelor

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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