Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

: A Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Mindfulness-Based Cognitive Therapy (MBCT) on Self-Esteem and Perceived Stress in Infertile Women

Protocol summary

Study aim

Compare the effectiveness of ACT and MBCT on self-esteem and perceived stress in infertile women

Design

. The study population consisted of all infertile women referring to the Reyhaneh Infertility Treatment Center in Ardabil from the first half to the second half of 2026. Using a non-probability volunteer sampling method, 45 participants will randomly assigned to three groups (two experimental groups and one control group). The experimental groups received the standard ACT and MBCT protocols, respectively, in eight 90-minute sessions.

Settings and conduct

“The Acceptance and Commitment Therapy and Mindfulness Therapy protocols will be administered during 8 weekly 90-minute sessions at the Reihaneh Infertility Center. This study is conducted as a single-blind trial; the outcome assessor will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

“Medical history of infertility (≥1 year); severe physical/psychiatric comorbidities precluding regular participation.”

Intervention groups

Intervention Group 1 (ACT):Participants in this group will receive the Acceptance and Commitment Therapy (ACT) protocol. This intervention consists of eight 45-minute sessions, focusing on key concepts such as acceptance, cognitive defusion, present-moment awareness, self-as-context, and values. Intervention Group 2 (MBCT):Participants in this group will receive the Mindfulness-Based Cognitive Therapy (MBCT) protocol. This program consists of eight 45-minute sessions, integrating mindfulness techniques with cognitive therapy principles, with a focus on non-judgmental awareness of present-moment experiences. Control Group (Waitlist):This study employs a waitlist control group design. Participants in this group will not receive any specific therapeutic intervention during the study period. considerations.

Main outcome variables

Self-esteem; Perceived stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260824070771N1**
Registration date: **2026-09-07, 1405/06/16**
Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**
Update count: **0**

Registration date

2026-09-07, 1405/06/16

Registrant information

Name

Fatemeh Shahbazi

Name of organization / entity

, Roudehen Branch, Islamic Azad University, Roudehen, Iran

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-11, 1405/06/20

Expected recruitment end date

2026-12-11, 1405/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: A Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Mindfulness-Based Cognitive Therapy (MBCT) on Self-Esteem and Perceived Stress in Infertile Women

Public title

Psychological interventions for infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20–45 years who had a medical record documenting infertility with their treating physician had experienced infertility for at least one year had a minimum educational level of junior high school were in good psychiatric health are willing to participate in the sessions

Exclusion criteria:

Presence of severe psychiatric disorders (e.g., psychosis, bipolar disorder, active suicidal ideation) that prevent group participation. Concurrent participation in any other structured psychological intervention or mindfulness-based training. Initiation or significant adjustment of psychotropic medication dosage within the last 3 month Current diagnosis of substance use disorder Presence of severe cognitive impairment interfering with the ability to understand and perform therapeutic exercises.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After screening and obtaining written informed consent, 45 eligible participants were enrolled. Participants were randomly assigned to three groups (Acceptance and Commitment Therapy, Mindfulness-Based Cognitive Therapy, and control) using random block randomization with a block size of 15, ensuring equal allocation (15 per group). A computer-generated random number sequence (SPSS; Random Number Generator) was produced by an independent statistician not involved in recruitment or intervention delivery. Group allocation was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE), which were opened only after baseline assessment was completed. Consequently, the outcome assessor and the intervention provider were blinded to the allocation sequence prior to assignment, ensuring allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will randomly assigned to the experimental and control groups using a lottery method. Due to the nature of the psychological interventions (MBCT and ACT), participants could not be blinded to the intervention; however, all assessments were conducted by an independent researcher who will blind to the group allocations (single-blind design)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Working Group, Islamic Azad University, Roudehen Branch

Street address

Paveh، Rudehen

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Roudehen

Province

Tehran

Postal code

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Approval date

2025-09-15, 1404/06/24

Ethics committee reference number

IR.IAU.R.REC.1404.022

Health conditions studied

1

Description of health condition studied

Perceived Stress in Infertile Women

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description
Self-esteem:Mean score on the Rosenberg Self-Esteem Scale (RSES; range 10–40about) after the intervention.
Timepoint
pretest, posttest, and a three-month follow-up
Method of measurement
the Rosenberg Self-Esteem Scale (RSES)

2

Description
Perceived stress:Mean score on the Cohen Perceived Stress Scale (PSS; range 0–40about) after the intervention.
Timepoint
pretest, posttest, and a three-month follow-up
Method of measurement
The Cohen Perceived Stress Scale (PSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1:The Acceptance and Commitment Therapy (ACT) protocol will be administered by the researcher to the experimental group in 8 sessions of 90 minutes each, held once per week. Immediately upon completion of the sessions, a post-test will be conducted, and a three-month follow-up assessment will be carried out for all groups after the end of the interventions.
Category
Rehabilitation

2

Description
Intervention Group 2:The Mindfulness-Based Cognitive Therapy (MBCT) protocol will be administered by the researcher to the experimental group in 8 sessions of 90 minutes each, held once per week. Immediately upon completion of the sessions, a post-test will be conducted, and a three-month follow-up assessment will be carried out for all groups after the end of the interventions.
Category
Rehabilitation

3

Description
Control group:The control group will not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Reyhaneh Infertility Treatment Center
Full name of responsible person
Fatemeh Shahbazi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Islamic Azad University, Roudehen Branch
Full name of responsible person
Marjan Nouri
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Fax
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Email
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Web page address
https://roudehen.iau.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The Islamic Azad University, Roudehen Branch
Proportion provided by this source
100
Public or private sector
Private
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

Roudehen Branch, Islamic Azad University, Roudehen, Iran

Full name of responsible person

Fatemeh Shahbazi

Position

PhD Student in Health Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the main results and outcomes are eligible for publication

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

Only researchers within the same discipline

From where data/document is obtainable

To my email address

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

Please contact me via email

Comments

No further explanation is provided