Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Mindfulness-Based Cognitive Behavioral Therapy Versus Usual Care in Reducing Anxiety and Improving Sperm Parameters (Count, Motility, and Morphology) in Infertile Men

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of MBCT in reducing anxiety and improving sperm parameters in infertile men.

Design

This study is a single-blind, parallel-group randomized controlled trial. Infertile men will be randomly allocated via an online randomization website to either MBCT (8 weekly 120-min sessions) or control (usual care without structured psychotherapy). The sample size is 60 (30 per group), and the trial is phase II.

Settings and conduct

Study Location: Psychological Sciences House Clinic, Mashhad, Iran. Study Population: Eligible infertile men meeting the inclusion criteria. Blinding Type: Single-blind. Blinding Method: Participants, outcome assessor, and data analyst are unaware of group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infertility diagnosis; high anxiety on the Spielberger scale; ≥5 years since diagnosis with ongoing condition; age 25–65; written informed consent.
Exclusion criteria: partner's pregnancy; psychiatric medication in the past 3 months; psychotherapy in the past 6 months; personality disorder or psychotic symptoms

Intervention groups

Intervention: MBCT (Group-based mindfulness-based cognitive behavioral therapy); 8 weekly 120-min group sessions, focusing on mindfulness practices (breathing, body scan, sitting meditation/mindful movement), reducing rumination and negative thoughts, cognitive restructuring and emotion regulation, plus daily home practice. Control (Usual care): Usual medical care and infertility follow-up only; no structured psychotherapy (brief stress-management info at baseline). MBCT offered after study.

Main outcome variables

State and trait anxiety scores based on the Spielberger State–Trait Anxiety Inventory (STAI); semen analysis parameters (sperm count, motility, and morphology)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251026067770N5**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date

2025-12-25, 1404/10/04

Registrant information

Name

fatemeh bardideh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

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
Comparing the Effectiveness of Mindfulness-Based Cognitive Behavioral Therapy Versus Usual Care in Reducing Anxiety and Improving Sperm Parameters (Count, Motility, and Morphology) in Infertile Men

Public title
Comparing Mindfulness-Based Cognitive Behavioral Therapy with Usual Care to Reduce Anxiety and Improve Sperm Measures in Infertile Men
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having a confirmed diagnosis of infertility by a specialist physician Obtaining a high score on the Spielberger State-Trait Anxiety Inventory (STAI) Providing informed consent to participate in the study Being between 25 and 65 years of age Having at least five years of infertility
Exclusion criteria:
Pregnancy of the spouse Lack of willingness to continue participation in the study Absence from more than three sessions Use of any psychiatric medication in the past three months, or participation in psychotherapy sessions within the past six months Presence of any personality disorder or transient psychotic features, as assessed by the Minnesota Multiphasic Personality Inventory (MMPI)
Age
From **25 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be conducted using the Randomization.com website. The random allocation sequence will be generated by an independent statistician who is not involved in study implementation or outcome assessment. Random permuted blocks with variable block sizes (4 and 6) will be used to maintain balance between the two groups: the “mindfulness-based cognitive behavioral therapy” group and the “no-intervention control” group. Allocation codes will be placed in sequentially numbered, sealed, opaque envelopes to ensure concealment of the random sequence until each participant is enrolled. Upon enrollment, the envelope corresponding to the participant’s order of entry will be opened by the staff member responsible for registration, and the participant will be assigned to the indicated group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Randomization will be performed using the website https://www.randomization.com.The random allocation list will be generated by a statistician who is not involved in participant recruitment or outcome assessment. A block randomization method with variable block sizes (4 and 6) will be used to ensure balanced group sizes between the Gestalt Therapy group and the no-intervention control group. The allocation codes will be sealed in opaque, sequentially numbered envelopes to maintain allocation concealment until each participant is enrolled. Upon enrollment, the next envelope in sequence will be opened by the registration officer, and the participant will be assigned to the corresponding group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Research Ethics Committee, Faculty of Medicine, Islamic Azad University, North Tehran Branch
Street address
5th Floor, Shahid Fakhrizadeh Research and Laboratory Building, Islamic Azad University, North Tehran Branch, Vafadar Boulevard, Shahid Sadooghi Street, Hakimiyeh Exit, Shahid Babayi Expressway (West to East)
City
Tehran
Province
Tehran
Postal code
1651153511
Approval date
2025-01-27, 1403/11/08
Ethics committee reference number
IR.IAU.TNB.REC.1403.248

Health conditions studied

1

Description of health condition studied
Male infertility
ICD-10 code
N46

ICD-10 code description
Male infertility

Primary outcomes

1

Description
Anxiety score on the State–Trait Anxiety Inventory (STAI) developed by Spielberger
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
Spielberger State-Trait Anxiety Inventory

2

Description
Sperm Count: Outcome description (English):Sperm count per milliliter of semen, measured through a standard laboratory semen analysis and reported in million/mL.
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
Sperm count is measured through a standard laboratory semen analysis performed according to the guidelines of the World Health Organization.

3

Description
Sperm Motility: Percentage of sperm with progressive and non-progressive motility, assessed according to WHO criteria in a standard semen analysis.
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
Sperm motility is assessed through microscopic examination of the semen sample as part of a standard semen analysis, following the criteria of the World Health Organization.

4

Description
Sperm Morphology: Percentage of sperm with normal morphology based on WHO standards, determined via microscopic examination of the semen sample.
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
Sperm morphology is evaluated through microscopic assessment of the semen sample based on the morphology criteria of the World Health Organization within a standard semen analysis.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group-based mindfulness-based cognitive therapy will be delivered in 8 weekly 120-minute sessions by a trained therapist. Sessions include mindfulness practices (body scan, mindful breathing, sitting meditation, mindful movement) integrated with cognitive–behavioral skills (identifying automatic thoughts/rumination, cognitive restructuring, emotion regulation), plus daily home practice (20–45 min) supported by guided audio and practice logs. Attendance and adherence will be recorded.
Category
Treatment - Other

2

Description
Control group: Participants in this group will receive usual medical care and routine clinical follow-up related to infertility, and no structured psychotherapy intervention will be provided. At baseline, they will be given brief general information on basic principles of stress management and mental health; however, no therapy sessions or structured training will be delivered. After completion of the study, participants in the control group will be offered the opportunity to take part in the mindfulness-based cognitive behavioral therapy program
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Home of Psychology Sciences
Full name of responsible person
Fatemeh Bardideh
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Phone
+98 76 9109 9071
Email
sup619001@iau.ir
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
10
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
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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
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
No - There is not 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
A data dictionary describing the structure of the dataset (variable names, coding schemes such as intervention group=1 and control group=0, score ranges for psychological instruments, and time points such as pre-test and post-test) will be made available after completion of data collection and publication of the primary results. This file contains only variable definitions and coding rules; it does not include any identifiable participant information.

When the data will become available and for how long
It will be available after completion of data collection and publication of the main study results in a scientific journal.

To whom data/document is available
Access will be granted only to qualified researchers who provide a written request and formally agree to a confidentiality commitment

Under which criteria data/document could be used
These data/documents may be used only for scientific and research purposes, such as methodological review, replication of the statistical analyses, or comparison with similar studies. Use for commercial purposes, attempts to re-identify participants, or any use outside a research context is not permitted. Access and use are conditional on a written commitment to confidentiality and non-disclosure.

From where data/document is obtainable
Requests should be directed to the Principal Investigator of the study: Naser Aghababaei, Assistant professor. Email: Naseragha@gmail.com. Access will be considered after scientific review of the request and a signed confidentiality commitment

What processes are involved for a request to access data/document
The requester must submit a written request to the Principal Investigator, including the research purpose, the specific data/document requested, and the intended use. The request will be reviewed for scientific merit and ethical compliance to ensure that use is strictly research-oriented and does not compromise participant confidentiality. If the request is approved, the requester will be asked to sign a confidentiality and non-disclosure agreement. After this agreement is signed, the shareable version of the data/document (with no identifying information) will be provided

Comments