Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of mindfulness based intervention on perceived stress and emotional intimacy of infertile couples

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based intervention on perceived stress and emotional intimacy of infertile couples

Design
Randomized clinical trial without blinding with an experimental group and a control group on 24 infertile couples.

Settings and conduct
location of the study will be Valiasr Clinic of Imam Khomeini Hospital .In addition to routine care, people in the intervention group will undergo exercises based on attention awareness.

Participants/Inclusion and exclusion criteria
Entry criteria: diagnosis of infertility in couples according to gynecologist opinion, presence of both spouses and having minimum literacy Exclusion criteria: use of psychological treatments or drug therapy for mental health problems

Intervention groups
Counseling sessions for the research units in the intervention group will be held for 8 weeks, one session a week, for 90 minutes, and these sessions include meditation and stretching, focusing on breathing, body scanning practice, paying attention to reactions to thoughts and feelings. During this period, the control group will not participate in any organized exercise program and will receive the center's routine care.

Main outcome variables
Perceived stress, emotional intimacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160821029446N14**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**
Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date
2025-11-18, 1404/08/27

Registrant information

Name
Maryam Damghanian

Name of organization / entity
Nursing and Midwifery Faculty, Tehran University of Medical Science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-02-21, 1404/12/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of mindfulness based intervention on perceived stress and emotional intimacy of infertile couples

Public title
Investigating the effectiveness of mindfulness based intervention on perceived stress and emotional intimacy of infertile couples

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of infertility in couples according to the gynecologist's opinion The presence of both couples Having at least reading and writing literacy
Exclusion criteria:
Using psychological treatments or drug therapy for mental health problems
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible individuals will be selected through convenience sampling and then assigned to the intervention and control groups using random block allocation with four-person blocks based on the sequences AABB, ABBA, ABAB, BBAA, BAAB, and BABA. In this method, the letter A represents the intervention group and the letter B represents the control group. All six permutations of the letters A, A, B, and B are written on six separate cards. Then, a number from 1 to 6 is randomly selected (using a random number table or by asking participant number 1 to randomly choose a card). For example, if number 2 is selected, it means that the first person will be assigned to the intervention group, the next two participants to the control group, and the fourth person to the intervention group. This process continues until the required sample size is reached. The intervention group will receive mindfulness training sessions in addition to routine infertility care, while the control group will receive only routine infertility care.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Keshavarz Blvd., Qods St. intersection, Tehran University of Medical Sciences Central Building
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2024-11-20, 1403/08/30
Ethics committee reference number
IR.TUMS.FNM.REC.1403.154

Health conditions studied

1

Description of health condition studied
Perceived stress, emotional intimacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Perceived stress
Timepoint
Before the start of the intervention, immediately after the intervention, two months after the intervention
Method of measurement
To examine the perceived stress, the 4-question questionnaire of perceived stress by Cohen et al. (1983), which is a shortened version, will be used. This 4-question questionnaire (2 positive items and 2 negative items) measures thoughts and feelings about stressful events, control and coping with psychological pressure and stress experienced during the last month. The scoring method of the questionnaire is based on a 5-point Likert scale (never = 0, low = 1, medium = 2, high = 3, very high = 4). Questions 2 and 3 are scored inversely, the lowest score is zero and the highest score is 16. A higher score indicates greater perceived stress.

2

Description
Emotional intimacy
Timepoint
Before the start of the intervention, immediately after the intervention, two months after the intervention
Method of measurement
Another tool is Walker and Thompson's (1983) 17-question emotional intimacy questionnaire. This questionnaire is designed to measure intimacy based on a seven-point Likert scale (never = 1, rarely = 2, sometimes = 3, often = 4, mostly = 5, almost always = 6, always = 7). and a higher score means more emotional intimacy in couples. The test scores are

obtained by summing the scores of the items and dividing it by the number 17. In this way, the minimum and maximum score of the subject is in the range of 1 to 7.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Counseling sessions for the research units in the intervention group will be held for 8 weeks, one session a week, for 90 minutes, and these sessions include meditation and stretching, focusing on breathing, body scanning practice, paying attention to reactions to thoughts and feelings.
Category
Lifestyle

2

Description
Control group: During this period, the control group will not participate in any organized exercise program and will receive the center's routine care.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr infertility treatment center
Full name of responsible person
Asal Ghavidel
Street address
Imam Khomeini Hospital
City
Tehran
Province
Tehran
Postal code
1473964431
Phone
+98 21 4250 0000
Email
Asalghavidel78@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Damghanian
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Keshavarz Boulevard, corner of Qods Street, Tehran University of Medical Sciences building
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Email
Vcmdrp@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Damghanian
Position
Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available