Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness on sexual dysfunction in women undergoing infertility treatment under the supervision of Iran University of Medical Sciences

Protocol summary

Study aim
Determining the effect of mindfulness on sexual dysfunction in women undergoing infertility treatments

Design
Clinical trial with control and random groups. On 42 people (in each group). 4-by-6 and 6-by-block blocking will be used for randomization.

Settings and conduct
Sampling will be done in infertility centers under the supervision of Iran University of Medical Sciences. The members of the intervention group will receive mindfulness sessions twice a week during 8 sessions of 30 minutes virtually (with university-approved social networks and live).

Participants/Inclusion and exclusion criteria
Entry condition: Be literate; Female age 18 to 45 years; Score less than 23 from the Women's Sexual Function Questionnaire; Non-smoking, substance abuse, alcohol and drugs that affect sexual function in couples; Lack of pelvic floor function disorders based on signs and symptoms Non entry condition: Doubt about pregnancy; suspected symptoms of covid 19 in couples at the time of entering the study and 4 weeks before; Occurrence of stressful experiences 3 months before the study

Intervention groups
For each group, mindfulness sessions will be held twice a week for 8 30-minute sessions online (with university-approved social networks and live). The control group will receive routine care.

Main outcome variables
The effect of mindfulness on sexual dysfunction in women undergoing infertility treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140823018903N3**
Registration date: **2022-08-20, 1401/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-20, 1401/05/29**
Update count: **0**

Registration date
2022-08-20, 1401/05/29

Registrant information

Name
Leila Neisani Samani

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8888 2846

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nneysani@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mindfulness on sexual dysfunction in

women undergoing infertility treatment under the supervision of Iran University of Medical Sciences

Public title
The effect of mindfulness on sexual dysfunction in women undergoing infertility treatment

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be literate Female age 18 to 45 years Score less than 23 from the Women's Sexual Function Questionnaire Non-smoking, substance abuse, alcohol and drugs that affect sexual function in couples Lack of pelvic floor function disorders based on signs and symptoms Having sex with your spouse during the last 6 months Have sex at least once a week Couples undergoing infertility medication No history of female participation in mindfulness classes No known disorders and mental illness No known neurological disorders and diseases The spouse does not have diabetes and other sexually transmitted diseases Do not take drugs that affect mental and sexual function in couples Monogamy

Exclusion criteria:
Absence from more than two sessions of mindfulness sessions Being away from your spouse for more than a week for any reason while studying Infection of covid19 in couples while studying Occurrence of stressful experiences during the study The need or request of the couple to continue the drug treatment with fertility supplements in the same treatment cycle

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by the method of 4 blocks with a ratio of 1:1, in this way, first we will form blocks of 4 for allocating the research units in the control and intervention groups with symbols A and B respectively, in such a way that a block of 4 from Through the table of random numbers in the order of A and B. Then, upon entering, each sample will be assigned to one of the A and B groups.

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 Iran University of Medical Sciences

Street address
Tehran Hemat Highway next to Milad Tower، 14535

City
tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2022-03-31, 1401/01/11

Ethics committee reference number
ir.iums.rec.1401.199

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determining the effect of mindfulness on sexual dysfunction in women undergoing infertility treatments

Timepoint
Before and one month after the intervention

Method of measurement
Female Sexual Function Index-FSFI

Secondary outcomes

empty

Intervention groups

1

Description
People in the intervention group receive mindfulness sessions in groups of 3-5 people for 8 sessions of 30 minutes.

Category
Treatment - Other

2

Description
receive routine care
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility centers under the auspices of Iran University of Medical Sciences - Tehran
Full name of responsible person
Leila Nissan Samani
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Tehran, Vali-e-Asr St., above Vanak Sq., Rashid Yasemi St., Iranian School of Nursing and Midwifery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology, Iran University of Medical Sciences
Street address
Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences
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info@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Leila Nissan Samani
Position
Lecturer
Latest degree
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Other areas of specialty/work
Midwifery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Individuals' personal social information will be kept strictly confidential and will not be disclosed.

When the data will become available and for how long

The access period will start immediately after the results are published in the journal.

To whom data/document is available

All students and researchers referring to databases

Under which criteria data/document could be used

The results of the research are available to all interested parties after the completion of the work in the form of an article in the journal

From where data/document is obtainable

databases

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

By searching keywords for research in databases

Comments