

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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)

Phone

+98 21 8888 2846

Email address

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

۱۴۳۹۶۱۴۵۳۵

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

Street address

Tehran, Vali-e-Asr St., above Vanak Sq., Rashid
Yasemi St., Iranian School of Nursing and Midwifery

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+98 21 4365 1000

Email

Neisani89@gmail.com

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

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Tehran, Hemmat Highway next to Milad Tower, Iran
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+98 21 86701

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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

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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