

# 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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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 updating data**

**Contact**

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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**