

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of mindfulness-based counseling on sexual performance and body image of menopause women

Protocol summary

Study aim

Determining the impact of mindfulness-based counseling on sexual function and body image in menopausal women

Design

The counseling intervention study has pre-test and post-test and has a control group and a sample size of 110 people who are divided into two intervention and control groups by a simple random method (lottery).there is no blinding

Settings and conduct

110 women between the ages of 45 and 60 who met the entry criteria after completing the sexual function and body image questionnaire in the clinics of Dilijan and obtaining the desired score were entered into the study and randomly divided into two intervention and control groups and the intervention group They will receive counseling based on the conscious mind for 8 weeks in 90 minute sessions and again the questionnaires will be completed immediately after the intervention and 2 months after the intervention by the women of both groups.

Participants/Inclusion and exclusion criteria

Postmenopausal women aged 45 to 60. Literacy. Iranian and residing in Delijan. Legally married and sexually active with spouse. Spouse residing in Delijan. Normal body mass index and overweight. Natural menopause. No alcohol and drug use and no severe marital conflict. No psychiatric and gynecological diseases and no sexual dysfunction in spouse. No genital and malignant surgery in the woman. And scoring less than 28 on the sexual function questionnaire.

Intervention groups

Postmenopausal women who meet the inclusion criteria will be randomly divided into intervention and control groups, and the intervention group will receive 8 weekly sessions of 90 minutes of mindfulness counseling, and the control group will receive routine menopause training.

Main outcome variables

The first outcome: sexual performance The second consequence: body image

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241021063452N1**

Registration date: **2025-06-12, 1404/03/22**

Registration timing: **retrospective**

Last update: **2025-06-12, 1404/03/22**

Update count: **0**

Registration date

2025-06-12, 1404/03/22

Registrant information

Name

tayyebe rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4425 0947

Email address

t.rostami@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of mindfulness-based counseling on sexual performance and body image of menopause women

Public title
The effect of mindfulness-based counseling on sexual performance and body image of menopause women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women between the ages of 45 and 60 having experience to participate in the study Iranian nationality and living in Dilijan. Natural menopause Reading and writing literacy Being single and having sex with a spouse, being monogamous and having a permanent marriage. The wife is employed in Dilijan city and the wife does not stay outside the city for a long time. Body mass index in normal and overweight range, The performance score according to the questionnaire is less than 28.

Exclusion criteria:
Absence of alcohol and drug use in a woman and her husband And the absence of gynecological and mental diseases and the absence of dysfunction in the wife. Absence of acute marital conflicts between couples. and the absence of genital and malignant surgeries (uterus, ovaries, and breasts). Failure to participate in similar counseling and treatment sessions during the last month. Absence of an unfortunate event within 3 months before the study.

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Basij sq

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2024-06-16, 1403/03/27

Ethics committee reference number

IR.ARAKMU.REC.1403.123

Health conditions studied

1

Description of health condition studied

Sexual Function And Body Image

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Function

Timepoint

Before intervention _Immediately after the intervention_Two months after the intervention

Method of measurement

Rozen Women's Sexual Performance Questionnaire

Secondary outcomes

1

Description

Body Image

Timepoint

Before intervention _Immediately after the intervention_Two months after the intervention

Method of measurement

Littleton's Body Image Fear Questionnaire

Intervention groups

1

Description

Intervention group: Mindfulness-based counseling sessions for the intervention group are held weekly for

eight weeks

Category

Other

2

Description

Control group: Women in this group only receive routine menopause care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Dilijan city

Full name of responsible person

Tayyebe rostami

Street address

Fazel Naraghi Blvd.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Behzad Khansarinejad

Street address

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research@arakmu.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Arak university medical science

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

Arak University of Medical Sciences

Full name of responsible person

Tayyebe Rostami

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr fereshte farzan azar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

NO. 28, Welayat Ave, Emamat Blv,

City

Delijan

Province**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

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

No - There is not 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