

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of mindfulness-based training on health related quality of life and female sexual distress in postmenopausal women

Protocol summary

Study aim

This study aims to evaluate the effectiveness of a Mindfulness-Based Stress Reduction (MBSR) program on sexual distress and health-related quality of life among postmenopausal women.

Design

This is a randomized controlled trial (RCT) with a pre-test, post-test, and 3-month follow-up design.

Settings and conduct

The study will be conducted at health centers affiliated with Ahvaz Jundishapur University of Medical Sciences. Recruitment and intervention delivery will be carried out by trained facilitators under supervision.

Participants/Inclusion and exclusion criteria

Participants will be naturally postmenopausal women aged 47–62 years, with 1 to 5 years since their last menstrual period. Inclusion criteria include: a score >11 on the FSDS-R questionnaire, being married, no physical limitations for mindfulness practice, and no similar interventions in the past 6 months. Exclusion criteria include: acute or chronic illness affecting menopausal symptoms, recent major life stressors, hormone therapy in the past 6 months, substance abuse, use of antipsychotics, or engagement in professional physical activity.

Intervention groups

The intervention group will participate in eight weekly 90-minute sessions of MBSR training. The sessions include body scan, mindful breathing, yoga-based movements, and group discussion. The control group will receive no intervention during the study period.

Main outcome variables

Primary outcomes include changes in sexual distress (measured by FSDS-R) and health-related quality of life (measured by SF-36) from baseline to post-intervention and 3-month follow-up.

General information

Reason for update

Dear Respected Director, At the end of 2015, due to my marriage, relocation from Ahvaz, subsequent pregnancy, the passing of my mother, and later my father's heart disease and surgery (along with the mild depression that naturally followed), I was unable to return to Ahvaz. After my circumstances and emotional state improved, I was finally able to resume my work and sampling in Ahvaz in 2019. Thank you for your understanding.

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121623344N2**
Registration date: **2016-05-07, 1395/02/18**
Registration timing: **prospective**

Last update: **2025-07-31, 1404/05/09**

Update count: **1**

Registration date

2016-05-07, 1395/02/18

Registrant information

Name

Masoomeh Yazdani Aliabadi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 911 157 1204

Email address

yazdani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Jundishapur University of Medical Science

Expected recruitment start date

2016-01-30, 1394/11/10
Expected recruitment end date
2016-06-30, 1395/04/10
Actual recruitment start date
2019-07-01, 1398/04/10
Actual recruitment end date
2019-12-01, 1398/09/10
Trial completion date
2019-12-01, 1398/09/10

Scientific title
The effect of mindfulness-based training on health related quality of life and female sexual distress in postmenopausal women

Public title
The effect of mindfulness-based training on health related quality of life and female sexual distress in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Eligible participants were naturally postmenopausal women aged 47–62 years, with 1 to 5 years since their last menstrual period. Additional inclusion criteria were: a score >11 on the FSDS-R questionnaire during pretest screening, being married, having no physical limitations for performing mindfulness exercises, and no prior participation in similar interventions within the previous six months.

Exclusion criteria:

Exclusion criteria included: presence of acute or chronic diseases or conditions affecting menopausal symptoms (e.g., thyroid disorders, cognitive impairment), recent adverse life events (within six months), use of hormone replacement therapy or topical estrogens (within six months), alcohol or drug abuse, antipsychotic medication use, and professional physical activity. Participants who missed more than two sessions, experienced a major stressor during the intervention, or expressed unwillingness to continue were withdrawn from the study.

Age
From **47 years** old to **62 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned to either the intervention or control group using permuted block randomization with varying block sizes of 4, 6, and 8. Due to the nature of the intervention, blinding of

participants and facilitators was not possible. However data analysts were blinded to group assignments.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analysts were blinded to group assignments.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Science

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.AJUMS.REC.1394. 564

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Health related quality of life

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

Health related quality of life(SF36)

2

Description

Female sexual distress

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

Female sexual distress scale(FSDS)

Secondary outcomes

1

Description

Physical functioning(PF)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

Questions 3 to 12 of SF36

2

Description

Role physical(RF)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

Questions 13 to 16 of SF36

3

Description

Role emotional(RE)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

Questions 17 to 19 of SF36

4

Description

Vitaity(VT)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

questions 23, 27, 29 and 31 of SF36

5

Description

Mental health(MH)

Timepoint

Before the intervention, Immediately after the

intervention, Three months after the intervention completion

Method of measurement

questions 24, 25, 26, 28 and 30 of SF36

6

Description

Social functioning

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

questions 20 and 32 of SF36

7

Description

Bodily pain(BP)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

questions 21 and 22 of SF36

8

Description

General health(GH)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

questions 1, 33 and 36 of SF36

9

Description

The Physical Component of Summary(PCS)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

PF+RF+BP+GH dimensions of SF36 Questionnaire

10

Description

The Mental Component Summary(MCS)

Timepoint

Before the intervention, Immediately after the intervention, Three months after the intervention completion

Method of measurement

SF+RE+MH+VT dimentions of SF36 Questionnaire

Intervention groups

1

Description

Intervention group: According to MBSR protocol (Jon Kabat-Zinn, 2014) mindfulness training will be performed just once a week, in 120 minutes and during 8 sessions for each of 5 groups.

Category

Behavior

2

Description

Control group: Because of ethical considerations, mindfulness training will be performed in 2 sessions, three months after the intervention and at the end of three stages of evaluation.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

East Health Centers of Ahvaz

Full name of responsible person

Masoomeh Yazdani Aliabadi

Street address

Golestan Blvd, Golestane Enghelab Dormitory of University of Medical Science

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3311 0000

Email

eduaum@ajums.ac.ir

2

Recruitment center

Name of recruitment center

West Health Centers of Ahvaz

Full name of responsible person

Masoomeh Yazdani Aliabadi

Street address

Golestan Blvd, Golestane Enghelab Dormitory of University of Medical Science

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3311 0000

Email

eduaum@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Dr. Nader Saki

Street address

Golestan Blvd, Ahvaz Jundishapur University of Medical Science

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3311 0000

Email

eduaum@ajums.ac.ir

Grant name

Grant code / Reference number

MARC-9407

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

Yes

Title of funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of 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

Tarbiat Modares University

Full name of responsible person

Masoomeh Yazdani Aliabadi

Position

Ph.D Student of Reproductive Health

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Jalal AleAhmad, Nasr bridge

City

Tehran

Province

Tehran
Postal code
-
Phone
00
Fax
Email
yazdani.mw89@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Science
Full name of responsible person
Dr. Mojgan Javadnoori
Position
PhD of Reproductive Health, Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Golestan Blvd, Golestane Enghelab Dormitory of
Jundishpur University of Medical Science
City
Ahvaz
Province
Khouzestan
Postal code
-
Phone
-
Fax
Email
mozghanjavadnoori@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Masoomeh Yazdani Aliabadi
Position
Ph.D Student of Reproductive Health
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
Jalal AleAhmad, Nasr bridge
City
Tehran
Province
Tehran
Postal code
-
Phone
00
Fax
Email
yazdani.mw89@gmail.com
Web page address

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

Concerning about data privacy

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