Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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

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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

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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

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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

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Masoomeh Yazdani Aliabadi

Position
Ph.D Student of Reproductive Health

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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
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