

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of mindfulness training on quality of life in postmenopause women

Protocol summary

Summary

This study has been conducted to investigate the effect of mindfulness training on quality of life in postmenopausal women. Menopause women in Ahvaz are the population of the study in this Randomized Control Trial. The samples of the study are the women with eligibility criteria and willingness to participate in this study. Inclusion criteria include: natural menopause, being married, between at least the first and at last the fifth years after the normal menstrual cycles' stop, low and moderate quality of life and being fluent in Persian. Exclusion criteria include: a self-report of concurrent or history of psychological disorders as well as taking antipsychotic medications, taking Hormone Replacement Therapy (HRT), occurrence of misadventure in the past six months, self-report of dependence on nicotine, alcohol, opioids and other psychotropic drugs and absences of more than two sessions. This RCT is recruiting 60 women (30 participants in each of the control and the intervention groups) from east and west health centers of Ahvaz. For the intervention group (5 groups comprising 6 participants), mindfulness training will be performed just once a week, in 120 minutes and during 8 sessions, according to MBSR protocol by Jon Kabat-Zinn in 2014. For the control group, three months after the intervention and at the end of three stages of evaluation, mindfulness training will be performed in 2 sessions, because of ethical considerations. All participants will complete Menopause Specific Quality of Life questionnaire before the intervention, immediately after the intervention and three months after the intervention completion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072523344N1**

Registration date: **2015-10-27, 1394/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-27, 1394/08/05

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

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness training on quality of life in postmenopause women

Public title

The effect of mindfulness training on quality of life in postmenopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Natural menopause(not because of drug consumption or surgery); Women between 47 to 62 years of age; Between at least the first and at last the fifth years after the normal absence of menstrual cycles; Low and moderate quality of life; Being married; Being fluent in Persian; Without any physical disability to do the techniques; This technique has not been used in the past six months. Exclusion Criteria: A self-report of concurrent or history of psychological disorders; Taking antipsychotic medications; Taking Hormone Replacement Therapy (HRT) or using vaginal estrogen in the past six months; Self-report of dependence on nicotine, alcohol, opioids and other psychotropic drugs; Occurrence of misadventure in the past six months; Absences of more than two sessions; Fill out the questionnaire incompletely; Unwillingness to participate in the study any more.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Ahvaz Jundishapur University of Medical Science

Street address

Khuzestan, Ahvaz, Golestan Blvd, Jundishapur University of Medical Science, Vice Chancellor for Research

City

Ahvaz

Postal code

-

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.AJUMS.REC.1394. 192

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**

Menopause Specific Quality of Life

Timepoint

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

Method of measurement

Menopause Specific Quality of Life Questionnaire

Secondary outcomes**1****Description**

Vasomotor domain

Timepoint

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

Method of measurement

Menopause Specific Quality of Life Questionnaire

2**Description**

Psycho-social domain

Timepoint

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

Method of measurement

Menopause Specific Quality of Life Questionnaire

3**Description**

Physical domain

Timepoint

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

completion
Method of measurement
Menopause Specific Quality of Life Questionnaire

4

Description

Sexual domain

Timepoint

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

Method of measurement

Menopause Specific Quality of Life 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

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

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

Grant name

Grant code / Reference number

-

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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

Other areas of specialty/work

Street address

Golestan Blvd, Golestane Enghelab Dormitory of Jundishpur University of Medical Science

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Yazdani_mw89@yahoo.com Yazdani.m@ajums.ac.ir

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

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Masoomeh Yazdani Aliabadi

Position

MSc. Student of Counseling in Midwifery

Other areas of specialty/work**Street address**Golestan Blvd, Golestane Enghelab Dormitory of
Jundishapur University of Medical Science**City**

Ahvaz

Postal code

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*