

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the Effects of Group and Individual Mindfulness-Based Cognitive Therapy on Happiness of Postmenopausal Women

Protocol summary

Study aim

The Effects of Group and Individual Mindfulness-Based Cognitive Therapy on Happiness of Postmenopausal Women will be compared.

Design

Random counseling intervention is controlled by pre-test, post-test and follow-up.

Settings and conduct

Sampling is done in Sadi health centers of Ahvaz and is randomized in blocks. Group and Individual Mindfulness-Based Cognitive Therapy will be conducted for the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes obtaining score lower than the cutoff score(40-42) from Happiness scale and scores 11-18 base on Beck Depression Inventory as mild depression, potential menopausal women aged 50-64 years, menopausal 1-5 years ago, basic literacy and willingness to cooperate in the study and exclusion criteria includes history of a medical disorders or physical motor disability, history of psychological and cognitive disorders that needed medication, smoking and substance abuse, mourning or having critical events during last 3 months and participating in any counseling programs during last year.

Intervention groups

24 of participants are located in group intervention that will be divided into two groups of 12 people. Mindfulness-Based Cognitive Therapy Intervention will be held for them as 90 minutes group sessions weekly for 8 weeks. Another 24 of participants will be in individual intervention part that intervention will be held for them as 90 minutes individual sessions weekly for 8 weeks.

Main outcome variables

Happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230724058911N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Basad Terikani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 2772

Email address

terikani.b@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-01-18, 1402/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Group and Individual Mindfulness-Based Cognitive Therapy on Happiness of Postmenopausal Women

Public title

the Effects of Group and Individual Mindfulness-Based Cognitive Therapy on Happiness of Postmenopausal Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

obtaining score lower than the cutoff score(40-42) from Happiness scale and scores 11-18 base on Beck Depression Inventory as mild depression potential menopause women aged 50-64 year menopausal 1-5 years ago basic literacy willingness to cooperate in the study

Exclusion criteria:

history of a medical disorders such as or physical motor disability history of psychological and cognitive disorders that needed medication smoking and substance abuse mourning or having critical events during last 3 months participating in any MBCT program during last year

Age

From **50 years** old to **64 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be block type. 12 blocks with a volume of 4 are used. In each block, two allocations for the group intervention and two allocations for the individual intervention are considered. Random sequencing will be generated by web-based randomization using the site (<https://www.sealedenvelope.com>). The generated sequence will also be centrally hidden so that the list of random assignment sequences is provided to someone outside the research team. As soon as a person is eligible to participate in the study, the researcher or sampler will contact the person who has the random assignment sequence and he or she will code the participants to enter the study according to the sequence list.

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 Ahvaz Jundishapoor University of Medical Sciences

Street address

Central Organization Building , Esfand Ave , Golestan Blvd , Golestan District

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.AJUMS.REC.1402.255

Health conditions studied

1

Description of health condition studied

Happiness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Happiness

Timepoint

pre- test, post test and follow up 4 weeks after intervention

Method of measurement

Oxford Happiness Inventory

Secondary outcomes

empty

Intervention groups

1

Description

24 of participants are located in group intervention that will be divided into two groups of 12 people. Mindfulness-Based Cognitive Therapy Intervention will be held for them as 90 minutes group sessions weekly for 8 weeks.

Category

Behavior

2

Description

Intervention group: Another 24 of participants will be in an individual intervention that intervention will be held for them as 90 minutes individual sessions weekly for 8 weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Saadi health center of Ahvaz

Full name of responsible person

Basaad Terikani

Street address

No. 138, St. 5, 22 Bahman Ave., Golestan Blvd.

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Postal code

6134995959

Phone

+98 916 602 8493

Email

bterikan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Research building, Ahvaz University Of Science
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itc@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Basaad Terikani

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data is potentially shareable after unidentified individuals

When the data will become available and for how long

After finishing the study and publishing in a reputable journal

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used for future studies

From where data/document is obtainable

Sending an email to corresponding author:
parvinabedi@gmail.com

What processes are involved for a request to access data/document

sending an email to the corresponding author. The request will be answered after a month.

Comments