

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

the effect of trans-theoretical model based physical activity training program on depression and anxiety in Postmenopausal Women

Protocol summary

decision-making related to physical activity

Study aim

The effect of trans-theoretical model based physical activity training program on depression and anxiety in postmenopausal women

Design

Postmenopausal women with the characteristics identified by the health center are then divided into control and intervention groups. The intervention group is divided into two random subgroups. The groups are parallel and the study is single-blind followed by the first intervention group in 5 groups. The first session is taught and the second intervention group in the next 5 sessions

Settings and conduct

How to work: Physical activity training for eligible people who have been allowed to intervene and in the health centers 1 and 2 of Shahid Beheshti University and the control group because training does not belong to them is our blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Postmenopausal women with an age range of 56-45 years. Willingness to cooperate with the study. Have at least basic literacy (reading and writing). Living in the study area. Do not have specific diseases and disorders. Taking herbal or chemical remedies to reduce menopausal symptoms in the past 1 month, exercising professionally

Intervention groups

Educational intervention: At the beginning of the study, individuals are randomly divided into intervention or control groups, then the intervention group is divided into two subgroups. People in stages 1 to 3 of behavior change are in one group and people in the stages of operation and maintenance are in another group. The intervention group receives training based on a meta-theoretical model of physical activity.

Main outcome variables

The level of anxiety and depression, the stage of change in behavior related to physical activity and self-efficacy related to physical activity and the balance score of

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200222046579N1**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Parisa Gholam bareshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 3898

Email address

parisagholami1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-10, 1399/01/22

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of trans-theoretical model based physical activity training program on depression and anxiety in Postmenopausal Women

Public title

the effect of physical activity training program on depression and anxiety in Postmenopausal Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Postmenopausal women aged 56-45 years Elementary literacy (reading and writing) Residence in the study area No use of herbal or chemical drugs to reduce menopausal symptoms in the past 1 month

Exclusion criteria:

Having certain diseases and disorders that cause lifestyle changes or physical activity such as cancer, diabetes, cardiovascular disease, disability, respiratory distress Exercise professionally

Age

From **45 years** old to **56 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and explanations: The stochasticization method is based on gradual references and having inclusion criteria and interest in participating in the study. Randomization unit: Individual Randomization layers: Random Allocation software type: Random Allocation software How to make a random sequence: Sequence Explanation about allocation concealment: Individuals included in the study, using a random method into two groups (intervention and control) Are allocated. Randomization sequences will be generated based on 4 random permutation blocks using a web-based software. The randomization sequence will be provided to the project manager and will be hidden from the person participating in the study and the evaluator's colleague to enter the study until the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, only researchers are aware of which group of intervention and control individuals are in, and individuals are not aware of which type of training they receive.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-11-01, 1398/08/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.810

Health conditions studied**1****Description of health condition studied**

depression and anxiety

ICD-10 code

F06.3

ICD-10 code description

Mood disorder due to known physiological condition

Primary outcomes**1****Description**

Level of anxiety

Timepoint

Before training and after 6 months

Method of measurement

Depression and physical activity questionnaire

2**Description**

Self-efficacy related to physical activity

Timepoint

Before training and after 6 months

Method of measurement

Depression and physical activity questionnaire

3

Description

Level of depression

Timepoint

Before training and after 6 months

Method of measurement

Depression and physical activity questionnaire

Secondary outcomes

1

Description

The amount of physical activity

Timepoint

Before and 6 months after training

Method of measurement

Questionnaire and number of correct answers

Intervention groups

1

Description

Intervention group 1: People who are in stages 1 to 3 of behavior change, training is 10 sessions per week, the first 5 sessions are held only for the first subgroup of the intervention and the next 5 sessions for all members of the intervention group. At the beginning, general information questionnaires, IPAQ physical activity and transtheoretical model constructs are completed for each person in person. The training is based on a transtheoretical model of physical activity. And at the end of each session, a summary of training is provided to individuals.

Category

Behavior

2

Description

Intervention group 2: People in the operation and maintenance stages, receiving 5 weekly training sessions, at the beginning of the work, general information questionnaires, IPAQ physical activity and transtheoretical model constructs for each person are completed in person. The training is based on a transtheoretical model of physical activity. And at the end of each session, a summary of training is provided to individuals.

Category

Behavior

3

Description

Control group: Control group: do not receive any training during the study.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences ,
Tehran North Health Center

Full name of responsible person

Sharif Turkmen Nejad

Street address

No. 216, Ishraqi Alley, Seyed Khandan Bridge, Shariati
St., Tehran, Iran

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shc_sbmu@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Vice Chancellor for Research and Technology, 5th
Floor, Building No. 2, Shahid Beheshti University of
Medical Sciences and Health Services, Next to
Taleghani Hospital, Shahid Ebays Arabi St., Yemen
St., Shahid Chamran Highway, Tehran, Iran

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1985717443

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Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Gholam bareshi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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