Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effects of eight weeks Aerobic Training and Vitamin E consumption on depression Severity and Some Mental Health Indicators in Women with Depressive Symptoms

Protocol summary

Study aim

Determining the effects of eight weeks of continuous aerobic exercise and vitamin E supplementation on depression severity, quality of life, self-confidence, sleep quality, self-concept, memory function, and general fatigue in women with depressive symptoms

Design

A controlled, parallel-group, single-blind, block-randomized clinical trial on 48 patients with depression. The website www.randomization.com will be used for randomization.

Settings and conduct

This study will be conducted at Razi University. First, the research variables will be measured. Then, 4 groups of participants in the study will receive the desired interventions. After the interventions are completed, the research variables will be measured again. In this study, participants will be blinded. Tablets similar to vitamin E tablets will be used as placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age range 18 to 50 years - Resident of Kermanshah city - Body mass index (BMI) less than 29.9 kg/m2 - Having depressive symptoms (score of 16 or higher on the Center for Epidemiological Studies Depression Scale) Exclusion criteria: - Presence of musculoskeletal abnormalities or disorders - Participation in a regular exercise program in the past 6 months - Taking supplements with anti-inflammatory properties

Intervention groups

1) Exercise + Vitamin E: Three aerobic exercise sessions per week for 8 weeks and daily vitamin E supplementation 2) Exercise + Placebo: Three aerobic exercise sessions per week for 8 weeks and daily placebo pill intake 3) Vitamin E: Daily vitamin E supplementation for 8 weeks 4) Control: Daily placebo pill intake for 8 weeks

Main outcome variables

Changes in depression severity, quality of life, sleep quality, self-concept, self-esteem, memory status, general fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250403065195N1**
Registration date: **2025-04-28, 1404/02/08**
Registration timing: **prospective**

Last update: **2025-04-28, 1404/02/08**
Update count: **0**

Registration date

2025-04-28, 1404/02/08

Registrant information

Name
Shiva Moradi
Name of organization / entity
The University of Razi
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-30, 1404/02/10

Expected recruitment end date

2025-06-21, 1404/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of eight weeks Aerobic Training and Vitamin E consumption on depression Severity and Some Mental Health Indicators in Women with Depressive Symptoms

Public title

Studying the effects of aerobic exercise and vitamin E on depression severity and mental health in women with depressive symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 50 years Resident of Kermanshah city Body mass index (BMI) less than 29.9 kg/m2 Having depressive symptoms (score of 16 or higher on the Center for Epidemiological Studies Depression Scale)

Exclusion criteria:

Presence of musculoskeletal abnormalities or disorders Participation in a regular exercise program in the past 6 months Taking supplements with anti-inflammatory properties

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used through the website www.randomization.com. For this purpose, first, each subject is assigned a number as a unique identification code and a 48-digit sequence (equal to the sample size) is created. Then, the names of the intervention groups including 1) exercise + vitamin E group; 2) exercise + placebo group; 3) vitamin E group; 4) control group will be defined in the relevant section of the website. After defining the groups and in order to prevent potential problems caused by blocking with fixed-size blocks, the method of randomly selecting blocks with different sizes will be used for blocking. In this case, with the sample size being known, the block sizes will be unequal and a multiple of the number of intervention groups (for example, blocks with sizes of 2, 4, 6 or 8). The website has the ability to randomly create sequences of blocks with different sizes. In the final step, by executing the Generate Plan command on the website, all subjects are randomly assigned to blocks of different sizes that themselves have a random sequence. Finally, by using the number (code) assigned to each subject and examining the blocks, the group of each subject will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study will be conducted in a single-blinded manner and participants will be kept blind to the intake of vitamin E or placebo, while due to the nature of exercise training, blinding will not be done in this case (exercise intervention). In order to blind the two groups that do not receive vitamin E tablets, tablets similar to vitamin E tablets in terms of appearance, smell, taste and color will be used as placebos, and information regarding vitamin E and placebo intake will be kept secret from the subjects.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Razi University Research Ethics Committee

Street address

Room 73, Faculty of Sport Sciences, Razi University, Daneshgah St., Taq Bostan

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2025-03-14, 1403/12/24

Ethics committee reference number

IR.RAZI.REC.1403.056

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description
Change in severity of depression
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Standard questionnaire of the Center for Epidemiological Studies

2

Description
Change in quality of life
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Use of the Mental Health Quality of Life (MHQoL) questionnaire

3

Description
Change in sleep quality
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Using the Pittsburgh Sleep Quality Questionnaire

4

Description
Self-concept review
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Using the Robson Self-Concept Questionnaire

5

Description
Change in self-esteem
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Using the Rosenberg Self-Esteem Scale

6

Description
Change in memory status
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Using the standard MCS questionnaire (Memory Complaints Scale) to assess memory status

Secondary outcomes

1

Description
General fatigue assessment
Timepoint
Before the start of the intervention and 8 weeks after the start of the intervention
Method of measurement
Using the Multidimensional Fatigue Index (MFI) questionnaire

Intervention groups

1

Description
Intervention group: Continuous aerobic exercise, including 3 training sessions per week for 8 weeks. In the first week, the exercises will be performed for 20 minutes at an intensity of 50% of the heart rate reserve, and the intensity and duration of the exercise will be gradually increased. Finally, in the eighth week, the duration of the exercises will be 40 minutes and the intensity of the exercises will be equivalent to 60% of the heart rate reserve. This group will also receive 15 mg of vitamin E daily in the form of oral tablets.
Category
Treatment - Drugs

2

Description
Intervention group: Continuous aerobic exercise, consisting of 3 training sessions per week for 8 weeks. In the first week, the exercises will be performed for 20 minutes at an intensity of 50% of the heart rate reserve, and the intensity and duration of the exercise will be gradually increased. Finally, in the eighth week, the duration of the exercises will be 40 minutes and the intensity of the exercises will be equivalent to 60% of the heart rate reserve. This group will also receive placebo pills, which are completely identical to vitamin E pills, daily.
Category
Treatment - Drugs

3

Description
Intervention group: This group will receive 15 mg of vitamin E in the form of oral tablets daily for 8 weeks.
Category
Treatment - Drugs

4

Description
Control group: This group will have a normal life for 8 weeks and during this period, they will receive placebo pills, which are completely identical to vitamin E pills,

daily.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi University

Full name of responsible person
Ehsan Amiri

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Room 73, Faculty of Sport Sciences, Razi University, Daneshgah St., Taq Bostan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Razi

Full name of responsible person
Keyvan Amini

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Grant name

Grant code / Reference number

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

Title of funding source
The University of Razi

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
The University of Razi

Full name of responsible person
Ehsan Amiri

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Web page address

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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared after de-identifying the subjects.

When the data will become available and for how long
3 months after results are published

To whom data/document is available
All persons upon formal request

Under which criteria data/document could be used
Meta-Analysis Studies

From where data/document is obtainable
If you need to receive documents, please send an email to Ehsan Amiri, a faculty member at Razi University, at the following email address: e.amiri@razi.ac.ir.

What processes are involved for a request to access data/document
In case of formal request, stating the relevant reasons and providing full details, the data will be sent via email after 72 hours.

Comments