

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effects of 8 weeks of aerobic exercise and vitamin D supplementation on serum levels of brain-derived neurotrophic factor, quality of life, and some cognitive and psychological indices in Migraine patients

Protocol summary

Study aim

Effect of 8 weeks of aerobic exercise and vitamin D supplementation on serum levels of brain-derived neurotrophic factor (BDNF), quality of life, severity, duration, and frequency of migraine attack, memory performance, cognitive impairment, depression severity, quality of sleep, and physical self-esteem in Migraine patients

Design

A randomized, single-blind clinical trial with a control group, parallel groups on 48 patients, block randomization via www.randomization.com

Settings and conduct

This study is conducted at Razi University. First, the study variables are measured, and then, 4 experimental groups perform the prescribed interventions. Then, the variables are measured again. Participants and investigators will be blinded and, tablets identical to vitamin D tablets will be used.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Not participation in regular exercise over the last 6 months Having Migraine without aura Getting the certification of no prohibition of participating in the exercise training program from a specialist Insufficient values of Vitamin D (20-29 nanograms/milliliter) Aged between 20 to 50 years
Exclusion Criteria: Any psychiatric disorders other than Migraine without aura Alcohol and other kinds of drug addiction Musculoskeletal disorders Cardiovascular and pulmonary diseases Refusal to give informed consent

Intervention groups

1) Exercise + Vitamin D: Aerobic exercise 3 times a week for 8 weeks and weekly supplementation of vitamin D 2) Exercise + Placebo: Aerobic exercise 3 times a week for 8 weeks and weekly consumption of placebo tablets; 3) Vitamin D: Weekly supplementation of vitamin D for 8 weeks; 4) Control: Weekly consumption of placebo for 8

weeks

Main outcome variables

Changes in brain-derived neurotrophic factor, quality of life, variables of migraine, memory, cognitive performance, depression, quality of sleep,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N3**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **retrospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Ehsan Amiri

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 83 3845 8428

Email address

e.amiri@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of 8 weeks of aerobic exercise and vitamin D supplementation on serum levels of brain-derived neurotrophic factor, quality of life, and some cognitive and psychological indices in Migraine patients

Public title
Effects of exercise training and vitamin D supplementation on Migraine

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Not participation in regular exercise over the last 6 months Having Migraine without aura confirmed by a specialist Getting the certification of no prohibition of participating in the exercise training program from a specialist Insufficient values of Vitamin D (20-29 nanograms/milliliter) Aged between 20 to 50 years

Exclusion criteria:

Any psychiatric disorders other than Migraine without aura Alcohol and other kinds of drug addiction Musculoskeletal disorder Cardiovascular and pulmonary diseases Refusal to give informed consent

Age
From **20 years** old to **50 years** old

Gender
Male

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, permuted block randomization via the www.randomization.com website will be used. To do so, first, a unique number will be allocated to each subject as the identifier code and, a 48-digit sequence (equal to sample size) will be created. Then, treatment labels including 1) Exercise + Vitamin D group; 2) Exercise + Placebo group; 3) Vitamin D group, and 4) Control group will be entered in the relevant section on the website. After defining the treatment groups and to avoid potential problems associated with equal block sizes, permuted block randomization with different block sizes will be applied. In this case, by knowing the sample size, the block sizes will be unequal and a multiple of the number of treatment groups (for example, block sizes of 2, 4, 6, or 8). The website has the ability to randomly specify the sequence of blocks with different sizes. In the

final step and upon performing the 'Generate Plan' on the website, all subjects will be randomly assigned to blocks of different sizes that already have a random sequence. Finally, the group (treatment) of each subject will be specified by the use of the identifier code and checking out the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is single-blind in which participants are blinded about receiving vitamin D or placebo while, based on the nature of exercise training, there will be no blinding for exercise interventions. For blinding 2 groups not receiving vitamin D, tablets with identical characteristics, color, taste, and smell with vitamin D tablets will be prepared as the placebo, and none of the subjects will be aware of the status of the supplementation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kermanshah Razi University

Street address

Room. 73, Faculty of Sport Sciences, Razi University, University Str, Taq-e-bostan, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2021-06-02, 1400/03/12

Ethics committee reference number

IR.RAZI.REC.1400.033

Health conditions studied

1

Description of health condition studied

Migraine without aura

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Change in serum levels of brain-derived neurotrophic factor

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By the use of blood sample and ELISA method

2

Description

Change in quality of life

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

World health organization standard quality of life questionnaire (short version)

3

Description

Changes in severity, duration, and frequency of Migraine attacks

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By the use of researcher-made questionnaire to record the pertinent variables of Migraine attacks

4

Description

Changes in memory performance

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By the use of Subjective Memory Complaints Scale

5

Description

Changes in cognitive performance

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By the use of Ascertain Dementia 8 (AD8) questionnaire

Secondary outcomes

1

Description

Changes in depression severity

Timepoint

Before starting the intervention, and 8 weeks after starting the intervention

Method of measurement

By the use of Beck's Depression Inventory

2

Description

Change in the quality of sleep

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Pittsburgh Sleep Quality Index

3

Description

Change in physical self-concept

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Physical self-concept questionnaire

Intervention groups

1

Description

Intervention group: continuous aerobic exercise for 8 weeks and 3 sessions per week. In the first week, the duration of training will be 20 minutes and the intensity will be 50% of heart rate reserve. Gradually, the time and intensity of training increase, and at week 8, the time of training will be 40 minutes and the intensity will be 60% of heart rate reserve. This group also receives 50000 International Units of vitamin D in the form of oral tablets every week.

Category

Other

2

Description

Intervention group: continuous aerobic exercise for 8 weeks and 3 sessions per week. In the first week, the duration of training will be 20 minutes and the intensity will be 50% of heart rate reserve. Gradually, the time and intensity of training increase, and at week 8, the time of training will be 40 minutes and the intensity will be 60% of heart rate reserve. This group also receives placebo tablets identical to vitamin D tablets every week.

Category

Other

3

Description

Intervention group: This group receives 50000 International Units of vitamin D in the form of oral tablets every week for 8 weeks.

Category

Other

4

Description

Control group: Normal life during the study plus receiving placebo tablets identical to vitamin D tablets every week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic

Full name of responsible person

Hojat Arian

Street address

Vali-e-Asr Clinic, Kashani St

City

Alashtar

Province

Lorestan

Postal code

6891814777

Phone

+98 66 3252 6276

Email

hojataryian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Dr. Farzad Veysi

Street address

University St, Taq-e-Bostan

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 4515

Email

veysi@razi.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi University

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

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 73, Faculty of Sport Sciences, Razi University, Taq-e-Bostan, University St., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3845 8428

Fax

Email

e.amiri@razi.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 73, Faculty of Sport Sciences, Razi University, Taq-e-Bostan, University St., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3845 8428

Fax

Email

e.amiri@razi.ac.ir

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

Razi University

Full name of responsible person

Ehsan Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 73, Faculty of Sport Sciences, Razi University,
Tagh-e-Bostan, University St., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3845 8428

Fax**Email**

e.amiri@razi.ac.ir

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 are shared after the de-identification of the participants

When the data will become available and for how long

3 months after publication

To whom data/document is available

All individuals upon formal request

Under which criteria data/document could be used

Data sharing requests are accepted for any purposes

From where data/document is obtainable

To obtain any data/document, please send an e-mail to Ehsan Amiri, a faculty member at Razi University, through the following e-mail address: e.amiri@razi.ac.ir

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

Upon formal request, mentioning due reasons, and providing full personality details, data will be sent after 72 h via e-mail

Comments