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
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Iran (Islamic Republic of)
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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 differents 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6714414971
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Email
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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
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
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Ehsan Amiri
Position
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Other areas of specialty/work
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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
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