Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect of 8 weeks continuous and sprint-interval aerobic training on serum brain-derived neurotrophic factor (BDNF)levels, quality of life, depression severity, and some psycho-cognitive indices in depressed men

Protocol summary

Study aim

Effect of 8 weeks of continuous and sprint-interval aerobic training on: 1. Serum levels of brain-derived neurotrophic factor 2. Quality of life 3. Depression severity 4. Cognitive flexibility 5. Self-confidence 6. Anxiety 7. Quality of sleep 8. Physical self-esteem In depressed men

Design

A randomized clinical trial with a control group, parallel groups design on 42 patients, using www.randomization.com for simple randomization

Settings and conduct

This study is conducted at the Faculty of Sport Sciences of Razi University, Kermanshah, Iran. After the familiarization session, the study variables are measured and then, experimental groups perform the training program 3 times a week for 8 weeks. After the termination of the intervention, the study variables are measured under similar conditions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Not participation in regular exercise training over the last 6 months 2. Having moderate depression confirmed by a specialist 3. Getting the certification of no prohibition of participating in the exercise training program from a specialist Exclusion Criteria: 1. Any other psychiatric disorder other than depression 2. Alcohol or substance addiction 3. Inability to perform exercise interventions 4. Cardiovascular and pulmonary diseases 5. Obesity (body mass index more than 30) 6. Refusal to give informed consent

Intervention groups

1. Continous aerobic group: this group performs continuous aerobic training 3 times a week for 8 weeks 2. Sprint-interval aerobic group: this group performs sprint-interval aerobic training 3 times a week for 8 weeks 3. Control group: this group follows its normal life during the project

Main outcome variables

Change in BDNF levels, Change in quality of life, Change in depression, Change in self-confidence, Change in anxiety, Change in quality of sleep, Change in physical self-concept,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210617051606N1**
Registration date: **2021-09-07, 1400/06/16**
Registration timing: **prospective**

Last update: **2021-09-07, 1400/06/16**
Update count: **0**

Registration date

2021-09-07, 1400/06/16

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

2021-09-11, 1400/06/20

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of 8 weeks continuous and sprint-interval aerobic training on serum brain-derived neurotrophic factor (BDNF)levels, quality of life, depression severity, and some psycho-cognitive indices in depressed men

Public title
Effect of exercise training on depression

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Not participation in regular exercise training over the last 6 months Having moderate depression confirmed by a specialist Getting the certification of no prohibition of participating in exercise training program from a specialist

Exclusion criteria:
Any other psychiatric disorder other than depression Alcohol or substance addiction Inability to perform exercise interventions Cardiovascular and pulmonary diseases Obesity (body mass index more than 30) Refusal to give informed consent

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

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

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 42-digit sequence (equal to sample size) will be created. Then, treatment labels including sprint-interval training group, continuous aerobic group, and 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 3, 6, or 9). 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)
Not blinded

Blinding description

Placebo
Not 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.1400.023

Health conditions studied

1

Description of health condition studied
Depression Disorder

ICD-10 code
F32.1

ICD-10 code description
Major depressive disorder, single episode, moderate

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
Change in depression severity
Timepoint
Before starting the intervention, and 8 weeks after starting the intervention
Method of measurement
Hamilton Depression Rating Scale

4

Description
Change in cognitive flexibility
Timepoint
Before starting the intervention, and 8 weeks after starting the intervention
Method of measurement
The 20-item cognitive flexibility inventory (Dennis and Vander Wal)

Secondary outcomes

1

Description
Change in physical self-concept
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
Physical self-concept questionnaire

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 anxiety
Timepoint
Before intervention and after 8 weeks of intervention
Method of measurement
Beck Anxiety Inventory

4

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

Intervention groups

1

Description
Intervention group 1: 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 the week 8, the time of training will be 40 minutes and the intensity will be 60% of heart rate reserve.
Category
Other

2

Description
Intervention group 2: sprint interval training for 8 weeks and 3 sessions per week. In the first week, training includes 4 bouts of all-out sprint with 120 seconds rest among bouts (1:6 work to recovery ratio). Gradually, the training load increases and at week 8, the training includes 8 bouts of all-out sprint with 60 seconds rest among bouts (1:2 work to recovery ratio).
Category
Other

3

Description
Control group: normal life during the study
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Private Clinic
Full name of responsible person
Dr. Alireza Seifoleslami
Street address
Floor 5, Dey Building, Haj Mohammad Taghi St, Parking-e-Shahrdari
City
Kermanshah
Province
Kermanshah
Postal code
6716741477
Phone

+98 83 3728 1637

Email
info@salamati24.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
Room 73. Faculty of Sport Sciences, Razi University, University St, Taq-e-Bostan, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3427 7609

Email
e.amiri@razi.ac.ir

Web page address
https://phe.razi.ac.ir/~e.amiri

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
Room 73. Faculty of Sport Sciences, Razi University, University St, Taq-e-Bostan, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3427 7609

Email
e.amiri@razi.ac.ir

Web page address
https://phe.razi.ac.ir/~e.amiri

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
Room 73. Faculty of Sport Sciences, Razi University, University St, Taq-e-Bostan, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code

6714414971

Phone

+98 83 3427 7609

Email

e.amiri@razi.ac.ir

Web page address

https://phe.razi.ac.ir/~e.amiri

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

Not applicable

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