Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Ehsan Amiri
Name of organization / entity
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Email address
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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

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Province

Kermanshah

Postal code

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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
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Sponsors / Funding sources

1

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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

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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
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