

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Investigation of the effects of transcranial direct current stimulation and dark chocolate supplementation on athletic and cognitive performance in normobaric hypoxia after inducing mental fatigue in men cyclists

Protocol summary

Study aim

Determining the effects of electrical stimulation of the brain and dark chocolate on physiological and cognitive function and perceptual responses during and after debilitating endurance activity in hypoxia And mental fatigue

Design

This research will have an intervention group and a control group, double-blind and randomized with a within-group design and counterbalancing. Latin square method and www.random.org site are used for randomization.

Settings and conduct

Hypoxia through the hypoxia device, mental fatigue with the Stroop test software, supplement (dark and white chocolate) and direct transcranial stimulation of the brain with the tDCS device. Razi University Faculty of Sports Science Laboratory. Subjects and the lead researcher will not be aware of the type of stimulation received in each session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 44 years Active cyclist under the supervision of Kermanshah city cycling board Regular cycling training in the last six months at least three sessions a week Obtaining a certificate of non-prohibition from participating in an exercise program from a physician Being right-handed. Criteria for barring entry to the research: Climbing to an altitude of over 2000 meters in the past month Having any cardiovascular, pulmonary and metabolic diseases The presence of implantable or pacemaker devices in the body Tobacco and alcohol consumption

Intervention groups

Intervention: It is a group that receives the interventions of anodal electrical stimulation, sham stimulation and dark chocolate. Control: the group that consumes white chocolate. Each subject will be randomly examined in

four conditions.

Main outcome variables

Time to exhaustion; Electromyography; Rate of perceived exertion; Sense of pleasure; Arousal; Reaction time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220417054556N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

parisa banaei

Name of organization / entity

Faculty of Sports Sciences, Razi University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-07-29, 1401/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of transcranial direct current stimulation and dark chocolate supplementation on athletic and cognitive performance in normobaric hypoxia after inducing mental fatigue in men cyclists

Public title

The effect of transcranial direct current stimulation and dark chocolate on cyclists' athletic and cognitive performance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Active cyclist under the supervision of Kermanshah city cycling board Regular cycling practice for the past six months at least three times a week Obtaining a certificate of non-prohibition from participating in an exercise program from a physician Being right-handed Age range 18 to 44 years

Exclusion criteria:

Age

From **18 years** old to **44 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the order of subjects' exposure to four different conditions, the Latin square method will be used. To do this, first using the site www.random.org, each subject will be randomly assigned a number between 1 and 12 as the identification code. Then, the English letters A, B, C, and D are assigned to the four intervention terms, and a Latin square with four rows and four columns is created. After creating the Latin square, participants 1 to 3 in the first row sequence, participants 4 to 6 in the second row sequence, participants 7 to 9 in the third row sequence, and participants 10 to 12 in the sequence Sequences will be placed in the fourth row.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and the researcher will not be aware of the type of stimulation received in each session and this information will be available only to someone outside the

research team until the end of the research. In order to conceal the order of receiving the stimulus from the researcher, all the steps related to randomly determining the order of receiving the stimulus in each subject will be performed by the same person outside the research team. Also, in order to hide the type of stimulation in each session of the subjects, the tDCS device is hidden from the subjects by a cover and the researcher will not be present in the laboratory during the installation of the electrodes and at the end of 20 minutes and the time of electrode separation.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Razi University

Street address

Razi University, Tagh-e-Bostan, University St.

City

kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.RAZI.REC.1401.005

Health conditions studied

1

Description of health condition studied

Hypoxia

ICD-10 code

ICD-10 code description

2

Description of health condition studied

mental fatigue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Endurance sports performance

Timepoint

Before starting the intervention and every 3 minutes from the beginning of the test to exhaustion in each session for 4 weeks

Method of measurement

The Astrand test for men is used to measure the maximum power output of the subjects.

2

Description

Cognitive function

Timepoint

Before starting the intervention and every 3 minutes from the beginning of the test to exhaustion in each session for 4 weeks

Method of measurement

A reaction time test is used.

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group: 2: sham stimulation-dark chocolate, 1: anodal stimulation-dark chocolate." . In both groups of stimulation, after installing the electrodes, the subjects will receive anodal and sham electrical stimulation with a intensity of 2 mA crosswise in a sitting position and one session per week (for 4 weeks) for 20 minutes. Chocolate supplement Bitter (467 kcal of dark chocolate (Nestle-70%) will also be received cross-over each week for four weeks.

Category

Prevention

2

Description

"Control group: 1:Anodal stimulation- White chocolate, 2:Sham stimulation-White chocolate." In both groups of stimulation, after installing the electrodes, the subjects will receive anodal and sham electrical stimulation with a intensity of 2 mA crosswise in a sitting position and one session per week (for 4 weeks) for 20 minutes. They will also receive white chocolate supplements ((487 kcal from Nestle white chocolate)) cross-over each week for four weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University

Full name of responsible person

Parisa Banaei

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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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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

Parisa Banaei
Position
Researcher
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Total data

When the data will become available and for how long

Start access 6 months after printing results

To whom data/document is available

researchers

Under which criteria data/document could be used

For meta-analytic research

From where data/document is obtainable

vahid tadibi

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

Maximum one month after application

Comments