

# 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)

##### Phone

+98 81 3492 3788

##### Email address

p.banayi@yahoo.com

##### 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](http://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

**Street address**

Razi University, University Street

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714414971

**Phone**

+98 83 3427 7605

**Email**

p.banayi@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Razi University

**Full name of responsible person**

Ali Heyrani

**Street address**

Razi University., Daneshgah St.,Taghbestan.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714414971

**Phone**

+98 83 3427 7605

**Email**

p.banayi@yahoo.com

**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  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Razi University., Faculty of Sports Sciences.,  
University Blvd., Taq Bostan,  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714414971  
**Phone**  
+98 83 3427 7605  
**Email**  
p.banayi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Razi University  
**Full name of responsible person**  
Vahid Tadibi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Razi University., Faculty of Sports Sciences.,  
University Blvd., Taq Bostan  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714414971  
**Phone**  
+98 83 3427 7605  
**Email**  
vtadibi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Razi University  
**Full name of responsible person**

Parisa Banaei  
**Position**  
Researcher  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Razi University., Faculty of Sports Sciences.,  
University Blvd., Taq Bostan  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714414971  
**Phone**  
+98 83 3427 7605  
**Email**  
p.banayi@yahoo.com

## 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