Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of performing mental exertion during submaximal exercise with different intensities on brain metabolism and cognitive function in overweight individuals: fNIRS study

Protocol summary

Study aim
Investigating the effect of mental exertion combined with submaximal exercise with different intensities on brain metabolism and cognitive performance in overweight people

Design
The statistical population of this research is available. The number of subjects will be 15 (specified by Gpower).

Settings and conduct
There are 2 sessions at Shahid Beheshti University's Faculty of Sports and Health Sciences. In these sessions, body composition will be taken with the IN BODY 770 device, as well as MFO and VO2max tests. Similar to this session, in the next session, MFO and VO2max tests will be taken with mental effort. 4 sessions will be held at the brain mapping center located in the campus of Technical Faculties of Tehran University, in which mental effort (10 minutes) is done in one session, followed by 3 minutes of warm-up with a bicycle and then 20 minutes of low-intensity cycling And after that, 5 minutes of rest and 10 minutes of mental effort will be done, and the same will be done in the next session, with the difference that the intensity will be moderate. It is the same in the last two sessions; with the difference that together with the 20-minute sports activity, the Stroop test is also performed. It should be noted that in all these steps, Fnirs registration will be done simultaneously in this center.

Participants/Inclusion and exclusion criteria
Age range between 20 and 45 years Being overweight (BMI above 25) Not having physical, brain and mental diseases Not taking medicine Lack of regular sports activity in the past year being right-handed

Intervention groups
Mental effort in different intensities of sports activity in brain metabolism in overweight and obese people

Main outcome variables
Evaluation of cerebral metabolism in different intensities of exercise activity; With and without mental effort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221011056149N1**
Registration date: **2022-11-11, 1401/08/20**
Registration timing: **prospective**

Last update: **2022-11-11, 1401/08/20**
Update count: **0**

Registration date
2022-11-11, 1401/08/20

Registrant information

Name
Samira Pourmirzaei Kouhbanani

Name of organization / entity
Shahid Beheshti University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-24, 1401/09/03

Expected recruitment end date
2023-03-16, 1401/12/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of performing mental exertion during submaximal exercise with different intensities on brain metabolism and cognitive function in overweight individuals: fNIRS study

Public title

The effects of performing mental exertion during submaximal exercise

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 45 years Overweight and obese people being right-handed

Exclusion criteria:

People who have physical, mental and brain diseases. People who take medicine. People who have had regular sports activities in the past year.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **6**

Each person participates in 6 sessions in this project: the first session of MFO and VO2MAX test without mental work, the second session of MFO and VO2MAX test with mental work, the third session of mental test (10 minutes) and after that 3 minutes of warm-up with a bicycle and then 20 minutes of cycling with low intensity and then 5 minutes of rest and again 10 minutes of mental test, the fourth session of mental test (10 minutes) and then 3 minutes of warming up with the bike and then 20 minutes of moderate intensity cycling and after that 5 minutes of rest and again 10 minutes of mental test, the fifth session of mental test (10 minutes) and then 3 minutes of warm-up with a bicycle and then 20 minutes of low-intensity cycling with a mental test and then 5 minutes of rest and 10 minutes again Mental test, the sixth session of mental test (10 minutes) and then 3 minutes of warm-up with a bicycle and then 20 minutes of moderate intensity bicycle with mental test and then 5 minutes of rest and again 10 minutes of mental test

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biological Research of Shahid Beheshti University

Street address

Shahid Beheshti University., Shahid Shahriari Square., Evin., Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-02-19, 1400/11/30

Ethics committee reference number

IR.SBU.REC.1400.268

Health conditions studied

1

Description of health condition studied

Overweight and obese

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Oxyhemoglobin

Timepoint

Before, during and after submaximal exercise

Method of measurement

Functional near-infrared spectroscopy, Rating of perceived exertion, Heart rate monitoring

2

Description

Deoxyhemoglobin

Timepoint

Before, during and after submaximal exercise

Method of measurement

Functional near-infrared spectroscopy, Rating of

perceived exertion, Heart rate monitoring

3

Description
Total hemoglobin
Timepoint
Before, during and after submaximal exercise
Method of measurement
Functional near-infrared spectroscopy, Rating of perceived exertion, Heart rate monitoring

4

Description
Maximum oxygen consumption
Timepoint
During a graded exercise test
Method of measurement
Respiratory gas analysis device, Rating of perceived exertion, Heart rate monitoring

5

Description
Maximum fat oxidation
Timepoint
During a graded exercise test
Method of measurement
Respiratory gas analysis device, Rating of perceived exertion, Heart rate monitoring

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: submaximal activity with moderate intensity (60% of the maximum wattage achieved in the previous two sessions) for 20 minutes, which is concurrent with mental effort (which is performed with the Stroop test), during which the Fnirs hat It is placed on the subject's head. It should be noted that before and after this test, a 10-minute flanker test is performed, during which the Fnirs cap measures brain metabolism.Also, the heart rate is recorded during the test with a polar heart rate monitor. The total test time is about 50 minutes.
Category
N/A

2

Description
The second intervention group: Submaximal activity with moderate intensity (60% of the maximum watts achieved in the previous two sessions) is performed for 20 minutes, during which the Fnirs hat is on the subject's head. It should be noted that before and After this test, a 10-minute flanker test is performed, during which the Fnirs hat measures brain metabolism. Also, the heart rate is recorded during the test with a polar heart rate monitor. The total test time is about 50 minutes.
Category
N/A

3

Description
The third intervention group: low-intensity submaximal activity (30% of the maximum wattage achieved in the previous two sessions) for 20 minutes, which is concurrent with mental effort (performed with the Stroop test), during which the Fnirs hat It is placed on the subject's head. It should be noted that before and after this test, a 10-minute flanker test is performed, during which the Fnirs cap measures brain metabolism. Also, the heart rate is recorded during the test with a polar heart rate monitor. The total test time is about 50 minutes.
Category
N/A

4

Description
The fourth intervention group: Submaximal activity with moderate intensity (60% of the maximum wattage achieved in the previous two sessions) is performed for 20 minutes, during which time the Fnirs hat is on the subject's head. It should be mentioned before and After this test, a 10-minute flanker test is performed, during which the Fnirs hat measures brain metabolism. Also, the heart rate is recorded during the test with a polar heart rate monitor. The total test time is about 50 minutes.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
National Brain Mapping Laboratory
Full name of responsible person
Samira Pourmirzaei Kouhbanani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National science foundation
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?
No
Title of funding source
صندوق حمایت از پژوهشگران و فناوران کشور
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
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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 further information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Results for the main outcomes will be shared.
When the data will become available and for how long
6 months after the publication of the article
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
After access, people only have the right to use the study protocol.
From where data/document is obtainable
Samira Pourmirzai Kohbanani will respond via email.
What processes are involved for a request to access data/document
After receiving the request and stating the reasons for the need for the data, the request will be answered within a maximum period of one month.
Comments