

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Survey of the effect of temperature reduction of prefrontal area on accuracy of visual sustained attention in two groups of intervention and control

Protocol summary

Study aim

Survey of the effect of temperature reduction of prefrontal area on accuracy of visual sustained attention in two groups of intervention and control students of Shiraz University of Medical Sciences

Design

Sample size: 38 male students of Shiraz University of Medical Sciences aged 20 to 35 years Two groups of intervention and control with equal number in each group Assignment of samples in two groups of control and intervention, randomly and by permutation block method

Settings and conduct

The scientific field of this project is neuroergonomics and the location of this research is in the Faculty of Modern Science of Shiraz University of Medical Sciences. This study is done in 3 phases. The first phase consists of primary physiological and cognitive assessments, the second phase involves reducing the temperature of the forehead in the intervention group and the third phase includes physiological and cognitive reassessment in both intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-The consent of the individual to participate in the study 2-Spend breakfast or 250 cc water 3-Adequate sleep for at least 6 hours before the assessment session 4-Having a normal binocular or 10/10 5-Obtain score 0 to 22 from the Goldberg & Hiller General Health Questionnaire 6-Male gender Exclusion criteria 1-Creation of headache in the prefrontal temperature reduction phase 2-Creation of anxiety state in the phase of temperature reduction of the prefrontal 3-Creation of nausea and dizziness in the prefrontal temperature reduction phase

Intervention groups

The intervention group includes students who receive interventions to reduce the temperature of the prefrontal

area. The control group includes students who do not receive intervention.

Main outcome variables

accuracy of visual sustained attention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181203041830N1**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name

sajad mohsenian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 8129

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mohsenian_sajad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey of the effect of temperature reduction of prefrontal area on accuracy of visual sustained attention in two groups of intervention and control

Public title
Effect of Brain temperature reduction on visual attention

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The informed consent of the individual to participate in the study Spend breakfast or 250 cc water Adequate sleep for at least 6 hours before the assessment session Having a normal binocular or 10/10 Male gender
Exclusion criteria:
 The absence of disease or brain damage The absence of heart problems No use of blood pressure regulating drugs The absence of acute and chronic sinusitis Missing migraine headache The absence of anxiety Do not drink alcohol, nicotine and coffee at least 24 hours before the assessment No drug abuse

Age
From **20 years** old to **35 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized blocks are assigned to control and intervention groups. Therefore, in this study, the block is formed and defined, and the layers and clusters are not considered. However, in this study, 19 binary blocks (38 observations) are used, while in order to be more cautious and prevent known The grandson of the intervention for the second person in each block will use 9 blocks of four and 1 binary block. It is worth noting that the order of the crash in each block is determined using the software R.

Blinding (investigator's opinion)
Single blinded

Blinding description
In single-blind design, since the subjects are not informed about the intended intervention, bias and error are controlled in the reports. This study is a one-way blind study. That is, although at the beginning of the study, the informed consent is completed by all the participants in the study, the individual himself does not know the type of intervention that will be used.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Street of Qasr al-Dasht - between the streets of Palestine and Mulla Sadra - Pillar 29 - Diamond building - 1st and 2nd floors of the building

City

Shiraz

Province

Fars

Postal code

novinmed@sums.ac.ir

Approval date

2019-01-13, 1397/10/23

Ethics committee reference number

IR.SUMS.REC.1397.998

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Visual sustained attention is the ability of the observer to detect non-recurrent and unpredictable triggers over a long period of time during cognitive work.

Timepoint

Assessment of persistent vision attention in the first, second and third phase of the study

Method of measurement

Visual sustained attention is evaluated by standardized test set-up of the CANTAB.

Secondary outcomes

1

Description

The skin temperature of the prefrontal area

Timepoint
In the first, second and third phase of the study

Method of measurement
Polygeraghy sensor

2

Description
The amount of blood flow of prefrontal cortex

Timepoint
In the first, second and third phase of the study

Method of measurement
Hemoencephalography device

Intervention groups

1

Description
Intervention group:Reducing the temperature of the prefrontal area for one hour is done to reduce the temperature of the prefrontal cortex by using a temperature-reducing device cap. The coolant temperature is 4 degrees Celsius.

Category
Other

2

Description
Control group: For this group, the temperature control device is covered on the forging area, but no coolant fluid is present in this coating (Placebo effect).

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz university of medical sciences

Full name of responsible person
sajad mohsenian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

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
Shiraz University of Medical Sciences

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
Shiraz University of Medical Sciences

Full name of responsible person
zahra zamanian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Ergonomics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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