Clinical Trial Protocol
Iranian Registry of Clinical Trials

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DEVELOPMENT OF A CORTICAL-THERMAL STIMULATION DEVICE (CTSD) TO REGULATE FRONTOPOLAR TEMPERATURE AND THE EXAMINATION OF ITS EFFECTS ON COGNITIVE FUNCTIONS; A PSYCHOMETRIC VALIDATION APPROACH

Protocol summary

Study aim

The goal of this study is Development of a Cortical-Thermal Stimulation Device to regulate prefrontal temperature, and examination of its effects on cognitive functions by using of CANTAB battery, qEEG and fNIRS.

Design

Clinical trial with control group, with parallel groups, single blind, randomized, phase 2-3 on 40 participants

Settings and conduct

Study location: Shiraz Neuroscience Laboratory and Simorgh Rehabilitation Clinic During the study, the intervention group received the device in the on state and the control group in the sham state (that is, the device turns off automatically after thirty seconds).

Participants/Inclusion and exclusion criteria

The healthy adult would be included in the study if they met the following criteria: First no significant of cognitive impairment and head trauma; stable medical condition and age range 18-40 years old; residence in Shiraz and being literate enough to cooperate with the examiners, point of Raven's Progressive Matrices would be above 90 The healthy adult would be excluded if any of the following conditions are observed; any neuropsychological disorders or medical disease, drug abuse or alcoholism.

Intervention groups

In order to investigate the effect of the CTSD on cognitive functions, two intervention and control groups were determined; that both groups received the device for thirty minutes (the control group received the device as a placebo) and at the same time performed the CANTAB cognitive test, before and after receiving the temperature stimulation, EEG and fNIRS recording Been.

Main outcome variables

The levels of cognitive functions, including: attention, memory and executive functions, as well as the communication map of the cognitive areas of the cerebral cortex and also the amount of oxygenated blood in the frontal pole were recorded in this study.

General information

Reason for update

Acronym

CTSD

IRCT registration information

IRCT registration number: **IRCT20220904055869N1**
Registration date: **2022-10-06, 1401/07/14**
Registration timing: **retrospective**

Last update: **2022-10-06, 1401/07/14**
Update count: **0**

Registration date

2022-10-06, 1401/07/14

Registrant information

Name

Roohollah Zahediannasb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 0535

Email address

roohollaz1991@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-07, 1401/01/18

Expected recruitment end date

2022-08-05, 1401/05/14

Actual recruitment start date

2022-04-07, 1401/01/18

Actual recruitment end date

2022-08-05, 1401/05/14

Trial completion date

2022-08-05, 1401/05/14

Scientific title

DEVELOPMENT OF A CORTICAL-THERMAL STIMULATION DEVICE (CTSD) TO REGULATE FRONTOPOLAR TEMPERATURE AND THE EXAMINATION OF ITS EFFECTS ON COGNITIVE FUNCTIONS; A PSYCHOMETRIC VALIDATION APPROACH

Public title

Effect of forehead cooling on cognitive functions.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

No significant of cognitive impairment and head trauma stable medical condition The age range 18-40 years old Residence in Shiraz Being literate enough to cooperate with the examiners The point of Raven's Progressive Matrices would be above 90

Exclusion criteria:

Observation of any neuropsychological disorder or medical illness Drug abuse or alcoholism

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized clinical trial (phase 2-3 study) in which subjects were assigned to sham (control group) or true (intervention group) CTSD intervention through simple randomization in 1:1 ratio. We wrote the numbers 1-40 on papers of the same size and put them in a closed paper envelope. Then, after the participant agreed to participate in the study, we randomly picked a number from the envelope. If the number we picked was an even number, the participant was placed in the intervention group, and if there was an odd number, he/she was placed in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

How to conduct the study (use of Cortical Thermal Stimulating Device) and how the device works were explained to the participants and the informed consent form was completed, but during the study, the intervention group received the device ON and the control group as a sham (that is, the device turns off automatically after thirty seconds)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shiraz University of Medical Sciences

Street address

No. 4, Esteghlal Blvd, Shiraz Town

City

Shiraz

Province

Fars

Postal code

7173686674

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.SUMS.REC.1400.734

Health conditions studied

1

Description of health condition studied

The regulation of frontopolar temperature to enhancement of cognitive functions in healthy adults.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of healthy adults in CANTAB battery

Timepoint

First to sixth sessions for half an hour simultaneously with temperature stimulation

Method of measurement

Cambridge Neuropsychological Test Automated Battery (CANTAB)

2

Description

The examination of oxygenated blood in the frontopolar area

Timepoint
Before and after the sessions 2-5 for three minutes
Method of measurement
functional Near InfraRed Spectroscopic (fNIRS)

3

Description
Brain map scores
Timepoint
Before and after the first and sixth session for 6 minutes
Method of measurement
quantitative Electroencephalogram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study was conducted in 6 half-hour sessions, with a 24-hour interval between each session, and in each session the Cortical Thermal Stimulation Device was used for the participants. the Cortical Thermal Stimulation Device (made in the Department of Neurosciences of Shiraz University of Medical Sciences) has a headband part that is tied on the forehead of people and when the device is on, the temperature of the headband is in a certain temperature is kept constant, and in this study, for the intervention group, the device is placed on the forehead of the people for 30 minutes and keeps the temperature of this area constant at 34 degrees Celsius. It should be noted that this temperature was chosen based on previous studies.
Category
Rehabilitation

2

Description
Control group: according to the intervention group, the headband of the Cortical Thermal Stimulation Device is placed on the forehead of the people and the device is turned on, but in this group, thirty seconds after the start, the device is automatically turned off.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuroscience Laboratory, shiraz university of medical science
Full name of responsible person
Mohammad Nami
Street address
Unit 402, Floor 3, Mahyar apartment, 4 Alley, Esteghlal Blvd, Shiraz, IRAN
City
shiraz
Province
Fars
Postal code
7173686674
Phone
+98 71 3230 0535
Email
roohollaz1991@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hadi Aligholi
Street address
Unit 402, Floor 3, Mahyar apartment, 4 Alley, Esteghlal Blvd, Shiraz, IRAN
City
Shiraz
Province
Fars
Postal code
7173686674
Phone
+98 71 3230 0535
Email
roohollaz1991@yahoo.com
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
Mohammad Nami
Position

Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
Unit 402, Floor 3, Mahyar apartment, 4 Alley, Esteghlal Blvd, Shiraz, IRAN
City
shiraz
Province
Fars
Postal code
7173686674
Phone
+98 71 3230 0535
Email
roohollaz1991@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Nami
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
Unit 402, Floor 3, Mahyar apartment, 4 Alley, Esteghlal Blvd, Shiraz, IRAN
City
Shiraz
Province
Fars
Postal code
7173686674
Phone
+98 71 3230 0535
Email
roohollaz1991@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Roohollah Zahediannasb
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Neuroscience
Street address
Unit 402, Floor 3, Mahyar apartment, 4 Alley, Esteghlal Blvd, Shiraz, IRAN
City
Shiraz
Province
Fars
Postal code
7173686674
Phone
+98 71 3230 0535
Email
roohollaz1991@yahoo.com

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
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of part of the data will be reported in the form of an article, and the rest of the data (quantitative EEG and fNIRS) will also be used as a database for signal processing after deidentifying people.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Using information as a database and signal processing
From where data/document is obtainable
Register action through roohollaz1991@yahoo.com
What processes are involved for a request to access data/document
Registering the request through the said email, identifying the person's identity and resume (to check employment in academic and scientific institutions), sending information
Comments