

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Design of neurofeedback machine framework based on brain signal irregularity to enhance working memory

Protocol summary

Study aim

1- To design a more effective neurofeedback system based on adaptive linear combination of features, 2- To evaluate the effectiveness of the proposed neurofeedback system.

Design

Randomized clinical trial, with control group, two-arm parallel groups, simple random allocation, intervention and control group: each 6 subjects.

Settings and conduct

This study focuses on the development of systems used to enhancement working memory, at Tarbiat Modares University of Iran. The procedure: I. Extraction of features to design a more effective neurofeedback protocol, II. Design and implement of neurofeedback system based on adaptive linear combination of features, III. Evaluate the system efficacy in memory enhancement compared with the conventional neurofeedback systems, including 1. Assessing static and dynamic working memory performance and recording baseline EEG in pretest session, 2. Conducting 10 neurofeedback training sessions, 3. Assessing static and dynamic working memory performance and recording baseline EEG in posttest session, 4. Evaluating both the results of working memory tests and EEG signals of pretest, posttest and training sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female, aged between 20 to 35 years, healthy, have normal or corrected-to-normal vision, university student, neurofeedback-novice. Exclusion criteria: Have history of neurological diseases, medication use.

Intervention groups

Intervention group: Neurofeedback based on adaptive linear combination of features. Control group: Conventional neurofeedback. All two groups: Ten training sessions, two sessions per week. With the aim of enhancing second lower Alpha power at Oz channel in two groups, while also decreasing permutation entropy

at Fz channel in intervention group.

Main outcome variables

Working memory performance, Brain neural activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046931N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

neda behzadfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-07-13, 1392/04/22

Expected recruitment end date

2013-11-13, 1392/08/22

Actual recruitment start date

2013-09-23, 1392/07/01

Actual recruitment end date

2014-01-21, 1392/11/01
Trial completion date
2014-03-11, 1392/12/20

Scientific title
Design of neurofeedback machine framework based on brain signal irregularity to enhance working memory

Public title
Design of neurofeedback machine framework to enhance working memory

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy Have normal or corrected-to-normal vision
University student Neurofeedback-novice.
Exclusion criteria:
Have history of neurological diseases Medication use

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **12**
Actual sample size reached: **12**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects are selected by random sampling from the community of healthy individuals. After meeting the inclusion and exclusion criteria of the study, they will be assigned by simple randomization method using a random number table into groups of study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal-Ale-Ahmad

City
Tehran
Province
Tehran
Postal code
14115-111
Approval date
2013-07-13, 1392/04/22
Ethics committee reference number
IR.TMU.REC.2005/D52, Dated: 13-07-2013

Health conditions studied

1

Description of health condition studied

Healthy individuals

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Working memory performance

Timepoint

Before the intervention in the pretest session, after the intervention in the posttest session

Method of measurement

Cognitive assessment of static and dynamic working memory

2

Description

Brain neural activity

Timepoint

Before the intervention in the pretest session, after the intervention in the posttest session

Method of measurement

Cognitive assessment of static and dynamic working memory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neurofeedback based on adaptive linear combination of features, through self-regulation of features' coefficients during training. With the aim of enhancing EEG second lower Alpha power at Oz channel and decreasing permutation entropy at Fz channel to improve memory, 10 training sessions including three ten-minutes training trials. Two sessions a week. The device FlexComp Infiniti (Thought Technology Ltd, Montreal, QC) with the software developed in this study

will be used.

Category

Rehabilitation

2

Description

Control group: Conventional neurofeedback. With the aim of enhancing EEG second lower Alpha power at Oz channel to improve memory. 10 training sessions including three ten-minutes training trials. Two sessions a week. The device FlexComp Infiniti (Thought Technology Ltd, Montreal, QC) with the software developed in this study will be used.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University

Full name of responsible person

Neda Behzadfar

Street address

Department of Medical Physics, Faculty of Medical Sciences, Tarbiat Modares University, Nasr Bridge, Jalal-Ale-Ahmad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoob Fathollahi

Street address

Vice Chancellor for Research and Technology, Tarbiat Modares University

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res@modares.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tarbiat Modares 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

Islamic Azad University, Najafabad Branch

Full name of responsible person

Neda Behzadfar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

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Medical Engineering

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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

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

Title and more details about the data/document

All participants' data, after anonymization, will be shared through local and international biosignal online databases. The study protocol, statistical analysis map and informed consent can also be shared.

When the data will become available and for how long

Data and documents will be available once the results are published for an unlimited period.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Commitment to mention the source of data and the name of principal investigator for any use, commitment not to use for clinical purposes

From where data/document is obtainable

Correspondence with the representative of principal investigator, Neda Behzadfar, with email address: behzadfar_neda@yahoo.com

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

Request review by the representative of principal investigator (2 weeks), sharing the application with the principal investigator (2 weeks), final statement by the representative of principal investigator

Comments