Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Design and Implement of Second-Generation Neurofeedback System Based on User's Visual Attention, and Evaluate its Efficacy in Memory Enhancement

Protocol summary

Study aim
Develop the next generation of neurofeedback systems with more efficacy and robustness

Design
Randomized clinical trial, with control group, four-arm parallel groups, simple random allocation, intervention group I,II = each 10 subjects, control group I,II = each 10 subjects.

Settings and conduct
This study focuses on the development of systems used to treat mental disorders and for mind empowering, at Tarbiat Modares University of Iran. The procedure: I. Design and implement of visual attention-based neurofeedback system with two novel training protocols, II. 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 six 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-graduated or student, neurofeedback-novice. Exclusion criteria: Have history of neurological diseases, medication use.

Intervention groups
Intervention group I: Visual attention-based neurofeedback with effective visual stimulus. Control group I: Conventional neurofeedback. Intervention group II: Visual attention-based neurofeedback with attentional capture mechanism. Control group II: Conventional neurofeedback by monitoring user's visual attention without attentional capture mechanism. All four groups: with the aim of enhancing EEG Alpha power at Oz channel, six 30 minutes training sessions over two weeks.

Main outcome variables
Working memory performance, brain neural activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200212046473N1**
Registration date: **2020-03-24, 1399/01/05**
Registration timing: **retrospective**

Last update: **2020-03-24, 1399/01/05**
Update count: **0**

Registration date
2020-03-24, 1399/01/05

Registrant information

Name
Zeynab Khodakarami

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

2017-09-21, 1396/06/30

Scientific title

Design and Implement of Second-Generation Neurofeedback System Based on User's Visual Attention, and Evaluate its Efficacy in Memory Enhancement

Public title

Design and implement of Visual Attention-Based Neurofeedback System

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 20 to 35 years Healthy Have normal or corrected-to-normal vision University-graduated or student Neurofeedback-novice

Exclusion criteria:

Have history of neurological diseases (e.g. migraine or epilepsy) 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: **40**

Actual sample size reached: **40**

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

2015-11-09, 1394/08/18

Ethics committee reference number

IR.TMU.REC.1394.164

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, during the intervention within neurofeedback training sessions, after the intervention in the posttest session

Method of measurement

Recording EEG signals

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: Visual attention-based neurofeedback with effective visual stimulus. With the aim of enhancing EEG Alpha power at Oz channel to improve memory, six 30 minutes training sessions over two weeks. 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 I: Conventional neurofeedback without monitoring user's visual attention. With the aim of enhancing EEG Alpha power at Oz channel to improve memory, six 30 minutes training sessions over two weeks. The device FlexComp Infiniti (Thought Technology Ltd, Montreal, QC) with the software developed in this study will be used.

Category

Rehabilitation

3

Description

Intervention group II: Visual attention-based neurofeedback with attentional capture mechanism. With the aim of enhancing EEG Alpha power at Oz channel to improve memory, six 30 minutes training sessions over two weeks. The device FlexComp Infiniti (Thought Technology Ltd, Montreal, QC) with the software developed in this study will be used.

Category

Rehabilitation

4

Description

Control group II: Conventional neurofeedback by monitoring user's visual attention without attentional capture mechanism. With the aim of enhancing EEG Alpha power at Oz channel to improve memory, six 30 minutes training sessions over two weeks. 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

Zeynab Khodakarami

Street address

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

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Email

z.khodakarami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cognitive Sciences and Technologies Council

Full name of responsible person

Majid Nili Ahmadabadi

Street address

No. 35, CSTC Building, Alvand St., Argentina Sq.

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info@cogc.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cognitive Sciences and Technologies Council

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

Shahed University

Full name of responsible person

Zeynab Khodakarami

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Medical Engineering

Street address

Biomedical Signal Processing Lab., Faculty of Engineering, Shahed University, Opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway

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Tehran

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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

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Medical Engineering

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Zeynab Khodakarami

Position
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Other areas of specialty/work
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, Zeynab Khodakarami, with email address: z.khodakarami@gmail.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