

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Investigating the effectiveness of neurofeedback treatment on quality of life and functional attention in patients with mild brain trauma in two control and intervention groups.

Protocol summary

Study aim

Investigating the effectiveness of neurofeedback treatment on the quality of life and functional attention of patients with mild traumatic brain injury

Design

A clinical trial with a control group, with parallel groups, randomized in a simple way

Settings and conduct

In the emergency Department of Taleghani Hospital, Kermanshah, neurofeedback treatment is performed on the intervention group using the neurofeedback device of Thought Technology Company. Before the intervention, the quality of life questionnaire (SF-36) and the computer-based attention test (ANT) are completed by the participants.

Participants/Inclusion and exclusion criteria

Patients' Glasgow Coma Scale (GCS) should be between 13 and 15 at the time of admission to the emergency department. Patients should be between 18 and 60 years old. Patients who have at least a diploma Patients who have a history of related diseases, mental disorders or substance abuse Patients who have experience of neurofeedback treatment. Patients who have been traumatized for more than six weeks

Intervention groups

In the intervention group, patients receive neurofeedback treatment during 20 sessions. while the control group does not receive this treatment

Main outcome variables

quality of life questionnaire (SF-36) ; the computer-based attention test (ANT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230717058819N1**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Adel Parvizi-Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3433 0349

Email address

adel.p1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of neurofeedback treatment on quality of life and functional attention in patients with mild brain trauma in two control and

intervention groups.

Public title

Evaluation of the effectiveness of neurofeedback therapy in patients with mild traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' Glasgow Coma Scale (GCS) should be between 13 and 15 at the time of admission to the emergency department. Patients should be between 18 and 60 years old. Patients who have at least a diploma

Exclusion criteria:

Patients who have a history of related diseases, mental disorders or substance abuse Patients who have experience of neurofeedback treatment. Patients who have been traumatized for more than six weeks

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization method, we place 72 participants in 12 groups including 6 patients, which are called blocks. Allocation of treatment and control in blocks is determined randomly and is done using Python programming language. The size of each block is 6 participants, 3 patients in each block are assigned to the control group and 3 patients to the treatment group.

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 AJA University of Medical sciences

Street address

Etemad zadeh Ave., Fatemi Gharbi Blvd.,

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Postal code

1411718541

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.AJAUMS.REC.1400.244

Health conditions studied

1

Description of health condition studied

mild traumatic brain injury

ICD-10 code

S06.0

ICD-10 code description

Concussion

Primary outcomes

1

Description

Quality of Life (SF-36)

Timepoint

Before intervention & Five weeks after intervention

Method of measurement

Quality of Life Questionnaire (SF-36)

2

Description

Continuous Attention Network

Timepoint

Before intervention & Five weeks after intervention

Method of measurement

Attention Network Task

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 sessions neurofeedback

Category

Rehabilitation

2

Description

Control group: 5 weeks without intervention

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Taleghani Hospital

Full name of responsible person

Adel Parvizi-Fard

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Shahid Beheshti Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr. Sharif Nahafi

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adel.p1372@gmail.com

Web page address

<https://medicine.ajaums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Adel Parvizi-Fard

Position

MA Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

MA Student

Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Statistical analyses, Python codes for attention test and SF-36 quality of life questionnaire

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

By expressing convincing reasons

From where data/document is obtainable

Correspondence with the responsible person

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

The request will be sent to the responsible person and if the request is convincing, the information will be provided to the requester.

Comments