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.,
City
Tehran
Province
Tehran
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
Street address
Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6715847167
Phone
+98 83 3836 7984
Email
adel.p1372@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr. Sharif Nahafi
Street address
Shahid Etemad zadeh Ave., Fatemi Gharbi Blvd
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8833 7919
Email
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
Medical Engineering
Street address
Atlasi Ave., Nokan Town
City
Kermanshah
Province
Kermanshah
Postal code
6744193349
Phone
+98 83 3433 0349
Email
adel.p1372@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr. Sharif Najafi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physical Medicine
Street address
Etemad zadeh Ave., West Fatemi Blvd.,
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 4382 2442
Email
adel.p1372@gmail.com

Person responsible for updating data

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
Medical Engineering
Street address
Atlasi AVe., NokanTown
City
Kermanshah
Province
Kermanshah
Postal code
6744193349
Phone
+98 83 3433 0349
Email
adel.p1372@gmail.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
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