

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of neuro-feedback on the concentration of the 12-18 years of old individual with autism spectrum disorder in comparison with typically developing individuals

Protocol summary

Study aim

Effect of neurofeedback on the concentration of ASD samples (12-18 years of old) Effect of neurofeedback on the communication skills of ASD samples (12-18 years of old)

Design

a case-control, non-randomized, one-blinded study design, 20 cases in each group, with age and sex matched control samples.

Settings and conduct

32-channel 10-20 recording system for neurofeedback study, an special game displayed on a monitor for four minutes, analyzing EEG parameters and change the game specification accordingly.

Participants/Inclusion and exclusion criteria

inclusion: cases diagnosed with ASD (DSM-V criteria) ASD in level 1 or 2 (High function cases) exclusion: hearing loss, poor eyesight, bilingual, neurologic disorder, brain structural damaged cases

Intervention groups

Intervention group: ASD cases in 12-18 years of old range, resident of Hamadan Control: normal developing age- and sex match samples. Intervention: 10 session of neurofeedback according to the EEG recording and analysis

Main outcome variables

Selective attention and communication skills of children with autism spectrum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221012056157N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Sajjad Farashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 850 1055

Email address

farashi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of neuro-feedback on the concentration of the 12-18 years of old individual with autism spectrum disorder in comparison with typically developing individuals

Public title

Neurofeedback effect on 12-18 years of old ASD samples

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:
Autism spectrum disorder subjects diagnosed with DSM-V criteria Without neurological disorders Age range of 12-18 Family satisfaction

Exclusion criteria:
Hearing loss, poor eyesight, Bilingual Neurological disorder such as schizophrenia, epilepsy, Brain tumor

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

(دانشگاه علوم پزشکی همدان (کمیته اخلاق در پژوهش

Street address

Shahih Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2022-03-22, 1401/01/02

Ethics committee reference number

IR.UMSHA.REC.1401.036

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorders

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

concentration

Timepoint

Before neurofeedback intervention, After 10 session neurofeedback intervention

Method of measurement

EEG analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ASD samples in 12-18 years of old range

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism spectrum disorder research center, Hamadan University of Medical Sciences

Full name of responsible person

Sajjad Farashi

Street address

Shahid Fahmideh Street, Hamadan university of medical sciences

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 918 850 1055

Email

sajjad_farashi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Vice chancellor for research and technology,
Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Street, Hamadan University of
Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 918 850 1055

Email

sajjad_farashi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sajjad Farashi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

Shahid Fahmideh street, Hamadan University of
Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 918 850 1055

Email

sajjad_farashi@yahoo.com

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sajjad Farashi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

Shahid Fahmideh street, Hamadan University of
Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 918 850 1055

Email

sajjad_farashi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sajjad Farashi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

Street address

Shahid Fahmideh street, Hamadan University of
Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 918 850 1055

Email

sajjad_farashi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Most of participants were disagree with data sharing
statement.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is 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

The EEG data and demographical data can be shared,

provided that the data be deidentified.

When the data will become available and for how long

After the study is completed and the research questions were answered, data will be deposited in data sharing repositories.

To whom data/document is available

Everyone

Under which criteria data/document could be used

Citation to the original work

From where data/document is obtainable

for example, Figshare

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

Nothing

Comments