

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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**

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**Province**

Hamadan

**Postal code**

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**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**

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**Email**

sajjad\_farashi@yahoo.com

**Person responsible for scientific  
inquiries**

**Contact**

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**Contact**

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**Full name of responsible person**

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**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**