

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation of the effectiveness of binaural beat stimuli on integrated auditory-visual sustained attention performance and electroencephalographic parameters in normal individuals aged 18-40 years

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of binaural beat stimuli on the integrated function of continuous auditory-visual attention and electroencephalographic components in normal individuals

##### Design

In this study, Integrated visual and auditory continuous function test and EEG will be used to evaluate the effect of the binaural beat stimuli on 22 normal right-handed individuals without neurological disorders.

##### Settings and conduct

In this study, the integrated auditory-visual sustained attention test and EEG will be performed with and without intervention in the rehabilitation faculty of the University of Medical Sciences, .

##### Participants/Inclusion and exclusion criteria

Normal hearing sensitivity; Right-handed; Rule out of neurological disorders; Rule out of ADHD according to DSM-V criteria (adults version)

##### Intervention groups

The binaural beat stimuli produced by the software will be used as the intervention. Integrated visual and auditory continuous function test and EEG will be used to evaluate the effect of the intervention.

##### Main outcome variables

Absolute power Relative power Functional communication

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111113008082N4**

Registration date: **2022-02-06, 1400/11/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-06, 1400/11/17**

Update count: **0**

##### Registration date

2022-02-06, 1400/11/17

##### Registrant information

###### Name

Ghassem Mohammadkhani

###### Name of organization / entity

Tehran university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7768 4889

###### Email address

mohamadkhani@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-07-22, 1401/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of binaural beat stimuli on integrated auditory-visual sustained attention performance and electroencephalographic parameters in normal individuals aged 18-40 years

##### Public title

Effect of binaural beat stimuli on integrated auditory-visual sustained attention performance and electroencephalographic parameters

#### **Purpose**

Basic science

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Normal hearing sensitivity Right-handed Rule out of neurological disorders Rule out of ADHD according to DSM-V criteria (adults version)

##### **Exclusion criteria:**

#### **Age**

From **18 years** old to **40 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **22**

#### **Randomization (investigator's opinion)**

N/A

#### **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**

Ethics Committees of Tehran University of Medical Sciences

###### **Street address**

No 226, corner of Ghods Street, Keshavarz Blvd, corner of Ghods Street, Tehran, IRAN

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1417653761

##### **Approval date**

2020-03-01, 1398/12/11

##### **Ethics committee reference number**

IR.TUMS.FNM.REC.1398.226

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Normal individuals

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Absolute power

##### **Timepoint**

With and without intervention

##### **Method of measurement**

Using EEG

#### **2**

##### **Description**

Relative power

##### **Timepoint**

With and without intervention

##### **Method of measurement**

Using MATLAB software

#### **3**

##### **Description**

Functional communication

##### **Timepoint**

With and without intervention

##### **Method of measurement**

Using LORETA software

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

The binaural beat stimuli as intervention will be produced using Audacity software. For this purpose we use two pure tones of 400 Hz and 416 Hz to create 16 Hz bands that are within the beta band range of the brain rhythm. Integrated auditory-visual sustained attention performance and EEG will be performed with and without the binaural beat stimuli.

##### **Category**

Behavior

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Faculty of Rehabilitation, Tehran University of Medical

Sciences

**Full name of responsible person**

Ghassem Mohammadkhani

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Ghassem Mohammadkhani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Audiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be 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