

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Study of the efficacy of theta binaural beat on the activity of brain waves in primary insomniacs

#### Protocol summary

##### Study aim

Purpose: Can theta binaural beat change the pattern of brain waves in primary insomniacs? If the theta binaural beat efficacy is shown to be based on the pattern of brain waves in primary insomniacs, they can be used to make other interventions in this field as a low-cost and non-invasive method.

##### Design

A clinical trial with a control group and the sample size of 24 12 patients in each group are enrolled in the study. In the experimental group, binaural beat and in the control group, white noise (as placebo) will be used for 15 minutes. A total of 25 minutes of brain waves are recorded for each patient, which is the first 5 minutes without music, then 15 minutes with music, and in the end 5 minutes without music.

##### Settings and conduct

This treatment consists of experimental and control groups. The experimental group receives the theta binaural beat and control group receives the White Noise. Each group consists of 12 people. The intervention is done individually and lasts for 25 minutes per person. Binaural beats exist at various frequencies, have shown that they can change brain waves. This study is without blindness. Intervention is done at Farabi Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent and willingness to participate in research, Diagnosis of primary insomnia in a clinical interview by a psychiatrist, Healthy physical and auditory condition Exclusion criteria: The occurrence of any physical and psychological warning signs such as headache, Unwillingness to continue protocol of intervention by the patient, such as shaking or talking, the annoying nature of the music used, Many artifacts during brain wave recordings

##### Intervention groups

In the experimental group, the theta binaural beat is used as an intervention, but in the control group, White Noise will be used as a placebo.

#### Main outcome variables

Theta and beta waves of the brain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038630N3**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

##### Registration date

2019-01-16, 1397/10/26

##### Registrant information

##### Name

Ali Akbar Foroughi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3837 4371

##### Email address

aliakbar.foroughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Study of the efficacy of theta binaural beat on the activity of brain waves in primary insomniacs

**Public title**

effect of theta binaural beat on primary insomniacs

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Informed consent and willingness to participate in research Evaluation of the index of insomnia severity index (ISI) at the clinical level (Score above 15) In order to enter the clinical interview Diagnosis of primary insomnia in a clinical interview by a psychiatrist The absence of severe neurological and psychiatric disorders Healthy physical and auditory condition No history of drug abuse Lack of cardiovascular problems Non-pregnant female participants Avoiding alcohol and drugs 12 hours before intervention

**Exclusion criteria:**

The annoying nature of the music used The occurrence of any physical and psychological warning signs such as headache Unwillingness to continue protocol of intervention by the patient Many artifacts during brain wave recordings, such as shaking or talking

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kermanshah University of

Medical Sciences

**Street address**

Parastar Blvd, faculty of medicine

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

9186364357

**Approval date**

2018-12-26, 1397/10/05

**Ethics committee reference number**

IR.KUMS.REC.1397.771

**Health conditions studied****1****Description of health condition studied**

Primary insomnia

**ICD-10 code**

F51.0

**ICD-10 code description**

Insomnia not due to a substance or known physiological condition

**Primary outcomes****1****Description**

brain wave pattern

**Timepoint**

Within 5 minutes before the intervention, 15 minutes during the intervention and 5 minutes later

**Method of measurement**

Electroencephalography (EEG)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Experimental group: Binaural beats are generated through Audacity software. The produced Binaural beat is at 6 Hz (theta) frequency. First, it is recorded for 5 minutes with closed eyes of the patient's brain waves through electroencephalography. Then, immediately for 15 minutes, with closed eyes, the theta binaural beat is heard through the headphones by the patient. In the final stage, the brain waves of the patient with closed eyes will be recorded for 5 minutes without receiving the binaural beat. For each patient, only one session is performed, which runs for the first 5 minutes as a pre-test, 15 second, post-test, and the last 5 minutes as follow-up.

**Category**

Treatment - Other

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### Description

Control group: White noise is a signal whose power density is the same at all frequencies. Such a sound will have all the audible frequencies of the same intensity. Therefore, they can be used as a placebo as in the research literature. First, it is recorded for 5 minutes with closed eyes of the patient's brain waves through electroencephalography. Then, immediately for 15 minutes, with closed eyes, the theta binaural beat is heard through the headphones by the patient. In the final stage, the brain waves of the patient with closed eyes will be recorded for 5 minutes without receiving the binaural beat. For each patient, only one session is performed, which runs for the first 5 minutes as a pre-test, 15 second, post-test, and the last 5 minutes as the follow-up.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farabi Hospital

##### Full name of responsible person

Habibollah khazaie

##### Street address

Dolatabad Blvd, Farabi Hospital

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

9186364357

##### Phone

+98 83 3836 7333

##### Email

amirpsy3@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Kermanshah University of Medical Sciences

##### Street address

Parastar Blvd, faculty of medical sciences

##### City

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##### Province

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##### Postal code

9186364357

##### Phone

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### Email

amirpsy3@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

#### Full name of responsible person

Amir Bavafa

#### Position

MSc student in clinical psychology

#### Latest degree

Bachelor

#### Other areas of specialty/work

Psychology

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amirpsy3@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Ali Akbar Foroughi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Psychology

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aliakbar.foroughi@kums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Ali Akbar Foroughi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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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**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

IPD collected for the primary outcome measure only,

**When the data will become available and for how long**

Start the access period from 1398

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

After qualification, any activity is subject to the observance of ethical standards

**From where data/document is obtainable**

amirpsy3@gmail.com Amir Bavafa +989158018060

Kermanshah, Parastar Blvd, Boostan enghelab dormity

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

The request is sent via e-mail and the information is sent within 1 month. Email: amirpsy3@gmail.com

**Comments**

I have no comments.