

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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+98 83 3837 4371

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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

2

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Kermanshah University of Medical Sciences

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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

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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Person responsible for scientific inquiries

Contact

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Ali Akbar Foroughi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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 dormitory

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.