Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effect of binaural beats on brain electrical activity, interleukin-6 serum levels and depression severity in patients referred to the psychiatric clinic of Imam Khomeini Jiroft Hospital with major depressive disorder in 2024: A Randomized controlled trial study

Protocol summary

Study aim

Determining the effect of binaural beats on brain electrical activity, interleukin-6 serum levels, and depression severity in patients referred to the psychiatric clinic of Imam Khomeini Jiroft Hospital with major depressive disorder in 2024: A Randomized controlled trial study

Design

A controlled, four intervention groups, parallel-group, single-blind, randomized clinical trial on 96 patients. A random number table was used for randomization.

Settings and conduct

The present research will be conducted as a randomized, single-blind clinical trial in Imam Khomeini Hospital, Jiroft.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 60 years; having healthy hearing function; have not been exposed to binaural bits stimulation; not having any neurological disease at present or previously; not consuming alcohol; not having an underlying disease; absence of pregnancy. Exclusion criteria: lack of healthy hearing function; has ever been stimulated by binaural bits for any reason; having a neurological disease at the moment or having a history of neurological disease; alcohol consumption; having an underlying disease; being pregnant

Intervention groups

The intervention group itself is divided into 4 subgroups: a) MDD patients treated with Binaural Delta Wave, b) MDD patients treated with Binaural Theta Wave, c) MDD patients treated with Binaural Aalpha Wave, d) MDD patients treated with Binaural Gamma Wave.

Main outcome variables

Electrical brain activity, Interleukin 6 Serum level, Severity of depression, Quality of Life, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230709058730N1**
Registration date: **2023-07-17, 1402/04/26**
Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**
Update count: **0**

Registration date

2023-07-17, 1402/04/26

Registrant information

Name

Mohammad Pourfridoni

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of binaural beats on brain electrical activity, interleukin-6 serum levels and depression severity in patients referred to the psychiatric clinic of Imam Khomeini Jiroft Hospital with major depressive disorder in 2024: A Randomized controlled trial study

Public title
Investigating the effect of binaural beats on brain electrical activity, interleukin-6 serum levels and depression severity in patients referred to the psychiatric clinic of Imam Khomeini Jiroft Hospital with major depressive disorder in 2024: A Randomized controlled trial study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with major depressive disorder (MDD) who have not received any treatment so far. The age range of patients should be between 20 and 60 years. Patients must have healthy hearing function. Patients should not have been exposed to binaural beats stimulation.

Exclusion criteria:
Having or history of any neurological disease Alcohol consumption The presence of any underlying disease Pregnancy

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done with a table of random numbers in such a way that the direction of reading the numbers in the table was determined from above. Numbers whose first two digits are between 00 and 12 belong to intervention group a, numbers whose first two digits are between 13 and 24 belong to intervention group b, numbers whose first two digits are between 25 and 36 belong to intervention group c, numbers which The first two digits of which are between 37 and 48 were assigned to the intervention group and the numbers whose first two digits are between 49 and 96 were assigned to the control group. Finally, one of the numbers in the table is randomly chosen and moved in the specified direction, and the numbers are recorded and assigned to study groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study is single-blind, so the participants (subjects) do not know which control or intervention groups they are in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Jiroft University of Medical Sciences

Street address
Pasdaran Blvd., Research and Technology Vice-Chancellor of Jiroft University of Medical Sciences

City
Jiroft

Province
Kerman

Postal code
۷۸۶۱۶۱۵۷۶۵

Approval date
2023-07-08, 1402/04/17

Ethics committee reference number
IR.JMU.REC.1402.041

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder

ICD-10 code
F32

ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Brain Electrical activity

Timepoint
The evaluation intervals of patients will be on day 0, day 14 and day 28.

Method of measurement
Electroencephalography

2

Description
Interleukin 6 Serum level

Timepoint
The evaluation intervals of patients will be on day 0, day 14 and day 28.
Method of measurement
ELISA laboratory kit

3

Description
Depression severity
Timepoint
The evaluation intervals of patients will be on day 0, day 14 and day 28.
Method of measurement
Patient Health Questionnaire (PHQ-9)

Secondary outcomes

1

Description
Quality of Life
Timepoint
The evaluation intervals of patients will be on day 0, day 14 and day 28.
Method of measurement
The World Health Organization Quality of Life – BREF (WHOQOL-BREF)

2

Description
Sleep quality
Timepoint
The evaluation intervals of patients will be on day 0, day 14 and day 28.
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Intervention groups

1

Description
Intervention group 1: patients with major depressive disorder who are treated with binaural beat delta wave with a frequency of 1 to 3 Hz. In addition to receiving their standard medical treatment (including Escitalopram 10 mg tablet daily), the patients listen to the specified frequency for 15 minutes every afternoon for 28 days. The frequency can be played for patients through the Frequency Sound Generator (Hoel Boedec) application, which is installed by the researcher on the patient's smart phone, and patients must use headphones to hear the frequency.
Category
Treatment - Other

2

Description
Intervention group 2: patients with major depressive disorder who are treated with binaural beat Theta wave with a frequency of 4 to 8 Hz. In addition to receiving their standard medical treatment (including Escitalopram 10 mg tablet daily), the patients listen to the specified frequency for 15 minutes every afternoon for 28 days. The frequency can be played for patients through the Frequency Sound Generator (Hoel Boedec) application, which is installed by the researcher on the patient's smart phone, and patients must use headphones to hear the frequency.
Category
Treatment - Other

3

Description
Intervention group 3: patients with major depressive disorder who are treated with binaural beat Aalpha wave with a frequency of 9 to 13 Hz. In addition to receiving their standard medical treatment (including Escitalopram 10 mg tablet daily), the patients listen to the specified frequency for 15 minutes every afternoon for 28 days. The frequency can be played for patients through the Frequency Sound Generator (Hoel Boedec) application, which is installed by the researcher on the patient's smart phone, and patients must use headphones to hear the frequency.
Category
Treatment - Other

4

Description
Intervention group 4: patients with major depressive disorder who are treated with binaural beat Gamma wave with a frequency of +30 Hz. In addition to receiving their standard medical treatment (including Escitalopram 10 mg tablet daily), the patients listen to the specified frequency for 15 minutes every afternoon for 28 days. The frequency can be played for patients through the Frequency Sound Generator (Hoel Boedec) application, which is installed by the researcher on the patient's smart phone, and patients must use headphones to hear the frequency.
Category
Treatment - Other

5

Description
Control group: The control group only receives the standard medical treatment of major depressive disorder, which includes the daily consumption of one tablet of Escitalopram 10 mg.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Khomeini hospital, Jiroft

Full name of responsible person
Hedyeh Askarpour

Street address
Shafa St

City
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Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Jeeroft 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
Jeeroft University of Medical Sciences

Full name of responsible person
Mohammad Pourfridoni

Position
MD Student

Latest degree
A Level or less

Other areas of specialty/work
Neurology

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Position
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Latest degree
A Level or less

Other areas of specialty/work
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Position
MD Student

Latest degree

A Level or less

Other areas of specialty/work

Neurology

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available