

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Investigating the effect of time-locked auditory with electrical brain stimulation on the day sleep microstructures and cognitive functions through meaningful stimulus-targeted reactivation from memory

Protocol summary

Study aim

Improving sleep quality and cognitive functions,
Psychotherapy in psychiatric disorders

Design

The sample size includes 131 people. 17 people are placed randomly in each group (8 groups). Randomization is done for intervention and control groups.

Settings and conduct

interventions will be performed 4 minutes after the subjects enter the N2 stage of sleep. The duration of simultaneous sound and electrical stimulation and the position of neutral and meaningful sound stimulation relative to electrical stimulation will be applied based on the findings of the first stage of the study. Sound stimulation is below the threshold of awakening (51.34 ± 2.75 dB) and does not wake up the person. For the purpose of blinding, the order of the sessions and the conceptual content of the meaningful sound stimulations will vary between individuals.

Participants/Inclusion and exclusion criteria

they are listed in general information section.

Intervention groups

The first group will receive electrical stimulation. In the second group, electrical stimulation will be applied simultaneously with sound stimulation. In the third group, only neutral sound stimulation will be applied rhythmically. In the fourth group, meaningful sound stimulation will be applied simultaneously with electrical stimulation. In the fifth group, meaningful sound stimulation will be applied rhythmically. In the sixth group, after the simultaneous acoustic and electrical stimulation, stimulations will stop and meaningful closed loop stimulation will be applied. In the seventh group, sound stimulation will be applied rhythmically. Then the sound stimulation will stop and meaningful close loop will be applied. The eighth group is the control group and will

not receive any stimulation.

Main outcome variables

Sleep quality, cognitive functions, salivary cortisol, K-complex, spindle waves and slow oscillations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230527058307N1**

Registration date: **2023-06-15, 1402/03/25**

Registration timing: **prospective**

Last update: **2023-06-15, 1402/03/25**

Update count: **0**

Registration date

2023-06-15, 1402/03/25

Registrant information

Name

Zahra Keshtgar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 915 663 5876

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of time-locked auditory with electrical brain stimulation on the day sleep microstructures and cognitive functions through meaningful stimulus-targeted reactivation from memory

Public title
Improving sleep quality and cognitive functions and psychotherapy during sleep

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The average body mass index is 23/0 kg/m² The average duration of normal sleep is 6-7 hours Obtaining a score of less than 6 in the PSQI questionnaire to evaluate the quality of sleep at night before the test session Having a regular sleep and wake rhythm (these two items are confirmed by using actigraphy or recording sleep and wake hours for 7 days before each intervention) lacking any known sleep disorders Not taking medicine during the test No smoking in the past year Avoiding any caffeinated beverages in the morning before the test sessions The normality of normal test results No history of psychiatric, endocrine, cardiac disorders Persian language
Exclusion criteria:
Diagnosed medical, psychiatric, and hearing disorders taking psychoactive drugs, narcotics or nicotine pregnant or lactating woman

Age
From **20 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **131**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study is done as restricted randomization. Because all the study groups have the same sample size. The restricted randomization method is also the law of random allocation. This method represents a large block for the entire sample size, which means that the balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, first, a total sample size will be determined and then a number of them will be randomly

placed in group A and the rest in group B. This method is used for two or more group experiments.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this project, neutral and meaningful sounds are presented during sleep and its effect on the depth and quality of sleep will be investigated. For this purpose, a group will not receive any sound and finally the changes in the brain waves of people in this group will be compared with receiving groups. In fact, everyone is taught sounds. But people do not know whether they are presented or not during sleep, and only the researcher who has to play the sounds knows about this.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

East Azerbaijan - Azadi St., Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.TBZMED.REC.1402.157

Health conditions studied

1

Description of health condition studied

Improving sleep quality and cognitive functions using simultaneous auditory and electrical stimulation, psychotherapy during sleep through meaningful auditory stimulation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

K-complex, spindle waves and slow oscillations

Timepoint

Before and after interventions

Method of measurement

examination of waves changes with fast Fourier transform method

2

Description

Stanford sleepiness scale questionnaire

Timepoint

Before and after interventions

Method of measurement

Comparison of scores of questionnaire with statistical method of paired t-test

3

Description

Positive and Negative Affect Schedule (PANAS)

Timepoint

Before and after interventions

Method of measurement

Comparison of scores of questionnaire with statistical method of paired t-test

4

Description

Pittsburgh Sleep Quality Index (PSQI)

Timepoint

Before and after interventions

Method of measurement

Comparison of scores of questionnaire with statistical method of paired t-test

5

Description

salivary cortisol

Timepoint

Before and after interventions

Method of measurement

changes in salivary cortisol level with statistical method of paired t-test

6

Description

cognitive functions (declarative memory, control of general alertness and vigilance, and investigation of sustained attention and reaction time)

Timepoint

Before and after interventions

Method of measurement

Comparison of individual performance in cognitive tasks(Paired Associate Learning(PAL), Psychomotor Vigilance Task (PVT)) with statistical method of paired t-test

Secondary outcomes

empty

Intervention groups

1

Description

The first group: Electrical stimulation

Category

Treatment - Devices

2

Description

The second group: Neutral rhythmic sound stimulation simultaneously with Electrical stimulation

Category

Treatment - Devices

3

Description

The third group: neutral rhythmic sound stimulation without electrical stimulation

Category

Treatment - Devices

4

Description

The fourth group: meaningful sound stimulation simultaneously with electrical stimulation

Category

Treatment - Devices

5

Description

The fifth group: meaningful rhythmic sound stimulation without electrical stimulation(meaningful rhythmic sound stimulation group)

Category

Treatment - Devices

6

Description

The sixth group: Neutral sound stimulation simultaneously with electrical stimulation, then stopping the two stimulations and using meaningful closed loop

Category

Treatment - Devices

7

Description

The seventh group: neutral sound stimulation without electrical stimulation and then stopping sound stimulation and the using of meaningful closed loop

Category

Treatment - Devices

8	Domestic
Description	Category of foreign source of funding
Control group	<i>empty</i>
Category	Country of origin
N/A	Type of organization providing the funding
	Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Mohammad Reza Saebipour

Street address
Ghaffari Street, Razi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

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
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin

Person responsible for general inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Mohammad Reza Saebipour

Position
University professor

Latest degree
Ph.D.

Other areas of specialty/work
sleep

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Keshtgar

Position

Ph.D. student

Latest degree

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Other areas of specialty/work

Speech therapy, Sleep

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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

The information collected before and after the intervention, as well as the changes in brain waves due to the desired intervention, can be shared while preserving the individual's personal information.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for the public freely.

Under which criteria data/document could be used

Bringing up the goals and reasons for requesting documents Bringing up the desired analysis on the requested data Mentioning the names of data collectors in reports or articles provided from the requested data Permitting the use of data in order to use appropriate treatment methods for the treatment of sleep disorders

From where data/document is obtainable

Mohammad Reza Saebipour: saebipour@gmail.com

Parviz Shahabi: parvizshahabi@gmail.com Zahra

Keshtgar:keshtgarz@gmail.com

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

By sending an email to one of the mentioned people, if all people agree, the data will be accessible to the applicant.

Comments