

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the Effect of Cranio-electrical stimulation (CES) on Depression, Anxiety and craving in people who received methadone maintenance treatment

Protocol summary

Study aim

Investigating the Effect of Cranio- Electrical Stimulation on Depression, Anxiety and craving in client with methadone maintenance treatment.

Design

A randomized, double-blind, randomized controlled clinical trial of 60 individuals receiving methadone maintenance treatment

Settings and conduct

The place of intervention and study steps in addiction treatment centers were randomly selected. Thirty people with the device turned on and thirty people with the device turned off are randomly checked by a third person outside the reader. The subjects do not know if the device is on or off. Researchers also do not know which person is in which category.

Participants/Inclusion and exclusion criteria

People on methadone treatment who are at least one month old from the start of methadone treatment, want to participate in the study, have no serious psychiatric problems, do not take psychiatric medication and have no history of head trauma and seizures are included in the study. People who test positive for urine during the study or those who do not want to continue studying are excluded from the study.

Intervention groups

The intervention group includes patients treated with methadone who receive clear device intervention. The comparison group includes patients treated with methadone who receive silent device intervention.

Main outcome variables

Hamilton Anxiety Score
Hamilton Depression Score
Examine substance craving

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051367N1**
Registration date: **2022-05-13, 1401/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-13, 1401/02/23**

Update count: **0**

Registration date

2022-05-13, 1401/02/23

Registrant information

Name

Homa Baghaei ravari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

homabaghaeiravari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Cranio-electrical stimulation

(CES) on Depression, Anxiety and craving in people who received methadone maintenance treatment

Public title

Investigating the Effect of Cranio-electrical stimulation (CES) on Depression, Anxiety and craving in people who received methadone maintenance treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

people with a history of addiction who are being treated with methadone in an addiction treatment center The first month of starting methadone treatment Willingness to participate in the study No serious psychiatric problem No use of psychiatric drugs No history of head trauma

Exclusion criteria:

Not Willingness to participate in the study serious psychiatric problem No treatment on methadone History of head trauma Use psychiatric drugs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant is not aware of whether the device is on or off. Also , the researcher and evaluator aren't aware with the device turned on and which with the device turned off

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research, school of medicine,

shahid beheshti university of medical sciences

Street address

next to taleghani hospital, arabi street, yemen street, chamran highway

City

tehran

Province

Tehran

Postal code

1985717434

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.SBMU.MSP.REC.1400.207

Health conditions studied

1

Description of health condition studied

major depression disorder

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode

2

Description of health condition studied

anxiety disorder

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

assessing the temptation to use drugs in the questionnaire to measure the temptation to use drugs after quitting/Primary consequence

Timepoint

beginning and end of study

Method of measurement

the questionnaire to measure the temptation to use drugs after quitting

Secondary outcomes

1

Description

depression score on the hamilton depression inventory

Timepoint

beginning and end of study

Method of measurement

hamilton depression inventory

2

Description

anxiety score on the hamilton anxiety inventory

Timepoint

beginning and end of study

Method of measurement

hamilton anxiety inventory

Intervention groups

1

Description

Intervention group: being treated with electrical brain stimulation in people receiving methadone maintenance treatment. The ATANG low frequency CES brand brain electrical stimulation device is model AT-9. The clear brain electrical stimulation device is used in the intervention group for eight weeks and three days a week, two sessions a day and each session for 30 minutes

Category

Treatment - Devices

2

Description

Control group: Silent electrical brain stimulation device is used in the control group for eight weeks and three days a week, two sessions a day and each session for 30 minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Ali kheradmand

Street address

Next to Shahid beheshti medical university, Shahid arabi street, Yemen street, Chamran highway

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1985711151

Phone

+98 21 2243 2560

Fax

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Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. afshin zarghi

Street address

fifth floor, sructure 2, shahid arabi st. , yemen st. , chamran highway

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1985717443

Phone

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Fax

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Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

homa baghaei ravari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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next to shahid beheshti medical university, shahid arabi st. ,yemen st. ,chamran highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Full name of responsible person
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Position
resident
Latest degree
Medical doctor
Other areas of specialty/work

Psychiatrics
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homabaghaeiravari@gmail.com

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

client's data is accessible with the exception of personal information

When the data will become available and for how long

access period starts six months after the results are published

To whom data/document is available

can be used for addiction treatment centers, psychiatrists and medical engineering researchers

Under which criteria data/document could be used

to use a cranio-electrical stimulation device in psychiatric studies

From where data/document is obtainable

homabaghaeiravari@gmail.com

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

send a message to the mentioned email or call 00989120220737

Comments