

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The study of neurofeedback effect on broken sleep, duration of sleep, restless leg syndrome changes and improvement of the quality of life HIV patients with sleep disorders.

Protocol summary

Study aim

Neurofeedback Effect on Sleep Disorders

Design

Open label clinical trials with two parallel groups; intervention and control groups

Settings and conduct

The HIV/AIDS patients in Emam Khomeyni Hospital are divided into two groups. Blood samples are taken from all of them to measure some factors; then performing the sleep test in the neurofeedback treatment group. the sleep test is done again after treatment.

Participants/Inclusion and exclusion criteria

Having at least 18 and maximum 50 years old; ability to read and write; lack of psychotic disorders based on clinical interviews; no use of hypnotic drugs; change of dose and the type of psychiatric medications of two months before entering the project until to end of the follow up period; not having history of seizure diagnostics one type of sleep disorders according to interviews and questionnaire

Intervention groups

A control group in this study can make decisions under the control of neurofeedback, and the other group can be control what they can without intervention

Main outcome variables

Polysomnography variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190620043954N1**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Khosroo sadeghniai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5546 0184

Email address

sadeghniai@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-29, 1397/08/07

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

2019-10-22, 1398/07/30

Actual recruitment end date

2020-06-20, 1399/03/31

Trial completion date

2020-06-20, 1399/03/31

Scientific title

The study of neurofeedback effect on broken sleep, duration of sleep, restless leg syndrome changes and improvement of the quality of life HIV patients with sleep disorders.

Public title

Treatment of Sleep Disorders with Neurofeedback

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least 18 years and maximum 50 years Ability to read and write Lack of psychotic disorders based on clinical interviews No use of hypnotic drugs A change of dose and the type of psychiatric medications of two months before entering the project until to end of the follow up period Not having history of Seizure Diagnostics one type of sleep disorders according to interviews and questionnaire

Exclusion criteria:

Lack of desire to continue treatment Treating ECT from entering of the project to follow up period To use of hypnotic drugs from entering of the project to end of follow up period Having seizures from entering of the project to follow up period Exacerbation of symptoms of HIV that they may not continue to the project

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The numbers from 1 to 30 is written on 30 papers and placed inside a bag. Each time a patient enters the study according to entry criteria, a paper is removed from the bag and the number that is written on the paper will be the number of intervention medication.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Porsina Ave, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-06-17, 1398/03/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.998

Health conditions studied

1

Description of health condition studied

Sleep Disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

Measurement of sleep quality

Timepoint

Before the onset of treatment and two weeks after starting treatment

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Improvement of sleep quality

Timepoint

Early (before the onset of treatment) and the end of the study (after the end of treatment)

Method of measurement

Polysomnography

2

Description

Interrupted sleep

Timepoint

Early (before the onset of treatment) and the end of the study (after the end of treatment)

Method of measurement

Polysomnography

3

Description

Time to fall asleep

Timepoint

Early (before the onset of treatment) and the end of the study (after the end of treatment)

Method of measurement

Polysomnography

4

Description

Restless leg syndrome

Timepoint

Early (before the onset of treatment)and the end of the study (after the end of treatment)

Method of measurement

Polysomnography

5

Description

Improving the quality of life

Timepoint

Early (before the onset of treatment)and the end of the study (after the end of treatment)

Method of measurement

HIV/AIDS - Quality of Life (HAT-QoL) questionnaire

Intervention groups

1

Description

Intervention group: 12 sessions of Neurofeedback treatment (20 minute,3 times a week)

Category

Treatment - Devices

2

Description

Control group: The control group does not receive the intervention and receives routine treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Iran AIDS Research Center

Full name of responsible person

Maryam Salehi

Street address

end of Keshavar Blvd - Imam Khomeini Hospital Complex- Back of Infection Building (Building 6) - Iran AIDS Research Center

City

Tehran

Province

Tehran

Postal code

73314119014

Phone

+98 21 6658 1583

Email

ircha@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran National Science Foundation

Full name of responsible person

Ms. Farhadi

Street address

Tehran Province, Tehran, Amir Abad, 5th St

City

Tehran

Province

Tehran

Postal code

13114-16846

Phone

+98 21 8216 1000

Email

support@insf.org

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Iran National Science Foundation

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**

Other

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Salehi

Position

Post - doctoral student

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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salehi-m@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available