

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Study of Neurofeedback Effect on Polysomnography Changes, Gene Expression of Hormone Receptors and Raising the Quality of Life of HIV+ Patients involved in Sleep Disorders

Protocol summary

Study aim

Neurofeedback Effect on Sleep Disorders

Design

The without blind clinical trials .

Settings and conduct

The patients with AIDS Emam Khomeyni Hospital are divided into two groups. Without blinded. 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 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

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

The study of treatment effect of sleep disturbance in neurofeedback method on Polysomnography Variables; hormone level ; gene Expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040686N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **retrospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Maryam Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1583

Email address

salehi-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-30, 1397/08/08

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-10-22, 1398/07/30

Actual recruitment end date

2020-05-08, 1399/02/19

Trial completion date

2020-05-08, 1399/02/19

Scientific title

The Study of Neurofeedback Effect on Polysomnography Changes, Gene Expression of Hormone Receptors and Raising the Quality of Life of HIV+ Patients involved in 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 Treatmenting ECT fromentering 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: **45**
 Actual sample size reached: **45**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The numbers from 1 to 45 is written on 45 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

2018-10-29, 1397/08/07

Ethics committee reference number

IR.TUMS.VCR.REC.1397.537

Health conditions studied

1

Description of health condition studied

Sleep Disorders

ICD-10 code

G 47.0

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

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

change in brain waves during sleep

Timepoint

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

Method of measurement

Polysomnography

6

Description

Cortisol hormone level

Timepoint

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

Method of measurement

ELISA

7

Description

Melatonin level

Timepoint

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

Method of measurement

ELISA

8

Description

Acetylcholine level

Timepoint

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

Method of measurement

ELISA

9

Description

Orexin level

Timepoint

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

Method of measurement

ELISA

10

Description

GABA level

Timepoint

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

Method of measurement

ELISA

11

Description

Expression of the glucocorticoid receptor gene

Timepoint

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

Method of measurement

PCR

12

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

13

Description

Expression of the Ach receptor gene

Timepoint

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

Method of measurement

PCR

14

Description

Expression of the Bmal1 receptor gene

Timepoint

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

Method of measurement

PCR

15

Description

Expression of the CLOCK receptor gene

Timepoint

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

Method of measurement

PCR

Intervention groups

1

Description

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

Category

Treatment - Devices

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

۷۳۳۱۴۱-۱۹-۱۴

Phone

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ircha@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

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?

Yes

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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Postal code

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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