

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The combination effect of cognitive rehabilitation and phototherapy on craving and cognitive functions of the clients of drug addiction clinics

Protocol summary

Study aim

Reducing drug cravings and improving brain function by phototherapy and brain rehabilitation

Design

This clinical trial has a control group with intersecting groups that is not corseted and individuals will be randomly divided into these 4 groups. This study will be performed in phase 3 on 84 patients and randomized software using random allocation software.

Settings and conduct

This study is a research in the field of addiction and will be conducted in opioid drug treatment centers. After obtaining the consent of the company in the research, the desired pre-tests will be performed, then the people will be randomly divided into 4 groups and phototherapy and cognitive rehabilitation interventions and the combined effect of these two therapeutic approaches will be performed. Then post-test evaluations will be performed and finally 2 months later they will be evaluated again to follow the treatment status.

Participants/Inclusion and exclusion criteria

In this study, people with acute psychiatric disorders or neurological disorders such as cerebral aneurysms, brain tumors, epilepsy, are not suitable for such therapeutic interventions and also from the entry of people with high blood pressure or pacemakers or substances The stimulus used is prevented. Admission Requirements: Referrals to addiction treatment clinics that use opioid drugs. Also, the age requirement for participating in the research is 18 to 60 years.

Intervention groups

This research has 4 main groups. One group will undergo cognitive rehabilitation treatment. One group will receive phototherapy. This group also has a placebo subset. The third group will receive both cognitive rehabilitation and phototherapy approaches. The fourth group is the control group on which no treatment will be performed.

Main outcome variables

independents: phototherapy , cognitive rehabilitation

dependents: substance craving , cognitive function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048759N1**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **prospective**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

Registration date

2021-12-15, 1400/09/24

Registrant information

Name

sayena hadadgar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8824 6126

Email address

hadad.phd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-23, 1400/10/02

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The combination effect of cognitive rehabilitation and phototherapy on craving and cognitive functions of the clients of drug addiction clinics

Public title
The effect of cognitive rehabilitation and phototherapy on craving and cognitive functions in opioid addiction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having the consent to participate in research Do not take psychiatric drugs Having the power of individual recognition and cognition Being 18 to 60 years old No deprivation or poisoning of drugs or narcotics
Exclusion criteria:
Use of stimulants and hallucinogens Female gender Acute neurological disorders Epilepsy, brain tumor, pacemaker, hypertension, visual and auditory impairment

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Karaj

Street address

Nu2/2, Ehsan Av, Satar khan bridge, Satar khan St.

City

tehran

Province

Tehran

Postal code
1454613431

Approval date
2020-10-11, 1399/07/20

Ethics committee reference number
ir.iau.k.rec.1399.054

Health conditions studied

1

Description of health condition studied

addiction

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

drug craving

Timepoint

This variable is measured before the phototherapy and brain rehabilitation intervention and after the interventions and 2 months later to follow the treatment status

Method of measurement

Instant and induced cravings and visual analog index tests

2

Description

brain functions

Timepoint

This variable is measured before the phototherapy and brain rehabilitation intervention and after the interventions and 2 months later to follow the treatment status

Method of measurement

Response inhibition is assessed with GO-NO-GO assessment software, risk-taking is assessed with Balloon Analogue Risk Task (BART) software, and emotion regulation is assessed by Panas positive and negative emotion testing.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group first undergoes 8 to 12 sessions of phototherapy and then undergoes 10 to 15 sessions of brain rehabilitation. Therapeutic sessions are twice a week. In phototherapy intervention, a low-power

RJ laser device made by the German company RJ is used to stimulate the frontal and peripheral lobes. Stop signal and Captain log software are used in brain rehabilitation intervention.

Category

Rehabilitation

2

Description

Intervention group 2: The second group is first treated with 10 to 15 sessions of brain rehabilitation treatment and then with 8 to 12 sessions of phototherapy. Therapeutic sessions are held twice a week. In phototherapy intervention, a low power RJ laser device made by the German company RJ is used to optically stimulate the frontal and peripheral lobes. Stop signal and Captain log software are used in brain rehabilitation intervention.

Category

Rehabilitation

3

Description

The control group will not receive any treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nik Teb Abuse Treatment Center

Full name of responsible person

Sayena Hadadgar

Street address

N2/2 , Ehsan Av, Satar khn St.

City

tehran

Province

Tehran

Postal code

1454613431

Phone

+98 21 8824 6126

Email

hadad.phd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hamed Sabet

Street address

N 2/2,Ehsan Av, Satar Khan St.

City

karaj

Province

Alborz

Postal code

3149968111

Phone

+98 26 3425 9576

Email

h-sabet@kiaau.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University of Karaj

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

Islamic Azad University

Full name of responsible person

Sayena Hadadgar

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

N 2/2, Ehsan Av. Satar Khan St.

City

Tehran

Province

Tehran

Postal code

1454613431

Phone

+98 21 8824 6126

Email

hadad.phd@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sayena Hadadgar

Position

Student

Latest degree

Master

Other areas of specialty/work

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City

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Phone

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

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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 more 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