

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the additive effect of transcranial direct current stimulation (tDCS) and Haboshefa in combination with conventional non-pharmacological therapies in reducing the temptation, improvement of cognitive ability and stress in cannabis users.

Protocol summary

Study aim

Evaluation of the additive effect of transcranial direct current stimulation (tDCS) and Haboshefa in combination with conventional non-pharmacological therapies in reducing the temptation, improvement of cognitive ability and stress in cannabis users.

Design

Randomized clinical trial with control group, double blinded, sham and placebo group beside real intervention, randomization executed with last number of national code.

Settings and conduct

Each patient randomly assigned to one group in depend on last number of national code. All patient with even number assigned to group A which receive standard therapy with TDCS. In this group we have two equal sub group received real TDCS therapy and sham TDCS therapy. Only the TDCS operator knows the real and sham and coding them means it remains blind to research team and the operator will not inform about patient follow up condition and psychological state which means double blind the research. Group B receive standard therapy with habolshafa capsules. In this group two sub group of real drug and placebo present which is blinded for research team and coded in sahed university.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-History of cannabis abuse for at least 6 months besides having the DSM-5 criteria of cannabis abuse disorder 2-Absence of any severe psychiatric comorbidity including schizophrenia -bipolar mood disorder 3- Age between 20 to 40 4-Male gender
Exclusion criteria: 1-Having other medical conditions such as Diabetes, Hypertension, Malignancy 2-Other substance abuse

Intervention groups

First intervention group received TDCS procedure (Half

real and half sham TDCS) in addition to standard therapy. Second intervention group received Habolshafa capsules (Half real capsules and half placebo capsules) in addition to standard therapy.

Main outcome variables

craving - memory - depression

General information

Reason for update

Acronym

کانابیس

IRCT registration information

IRCT registration number: **IRCT20220823055784N1**

Registration date: **2022-09-12, 1401/06/21**

Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**

Update count: **0**

Registration date

2022-09-12, 1401/06/21

Registrant information

Name

yasha fayaz faizy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3221 9703

Email address

dr_yasha_fayaz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the additive effect of transcranial direct current stimulation (tDCS) and Haboshefa in combination with conventional non-pharmacological therapies in reducing the temptation, improvement of cognitive ability and stress in cannabis users.

Public title

Evaluation of the additive effect of transcranial direct current stimulation (tDCS) and Haboshefa in combination with conventional non-pharmacological therapies in reducing the temptation, improvement of cognitive ability and stress in cannabis users.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Presence of cannabis abuse criteria at least for 6 months
Absence of any other obvious psychiatric disorder such as bipolar or etc. Age between 20 and 40 Male gender

Exclusion criteria:

Presence of underlying medical disease such as diabetes or malignancy or hypertension
Any other drug abuse

AgeFrom **20 years** old to **40 years** old**Gender**

Male

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

If the last number of national code (identity number) is odd, The patient will be in the TDCS group; And if it is even the patient will be in habolshafa group

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug packs are coded in two forms of real drug and placebo in the Shahed university, And the investigation team is not informed about the codes. In the TDCS group the patients are coded in two groups and only the operator has the information about the codes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran university medical ethic comitee

Street address

No.31 bakhshdari ave., thaleghani street, karaj

City

karaj

Province

Alborz

Postal code

۳۱۵۵۶۶۶۷۳

Approval date

2022-03-04, 1400/12/13

Ethics committee reference number

ir.iums.rec.1400.1147

Health conditions studied**1****Description of health condition studied**

cannabis abuse

ICD-10 code

F12.1

ICD-10 code description

Cannabis abuse

Primary outcomes**1****Description**

Craving

Timepoint

Start and end of study

Method of measurement

MCQ

2**Description**

Memory

Timepoint

Start and end of study

Method of measurement

Wechsler memory exam

3

Description

Depression

Timepoint

Start and end of study

Method of measurement

Hamilton depression exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: TDCS procedure perform in 20 session with standard protocol of craving reduction in DLPFC .Half patient receive real TDCS and other half sham TDCS .In this method single canal stimulation which Anod placed in F3 region and Cathod placed in F4 region is performed by previous studies .Duration of each session is 20 minutes and 2 MA stimulation will perform if tolerated.2 outpatient session each week present beside of standard psychological thrapy.Urine test perform weekly for cannabis depend on it`s halflife.

Category

Treatment - Devices

2

Description

Intervention group2 :Receive Habolshafa capsules weekly and consume 3 capsules per day each 8 hour .Drug packs contains 21 capsules each week .Real and placebo capsules coded in Shahed university without information to patient and research team .Duration of treatment is 12 week according to previous studies .Each week patients examined for drug adverse effect and urine cannabis test by the research team.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor fayaz drug abuse treatment center

Full name of responsible person

yasha fayaz faizy

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No.31 ,bakhshdari ave.,taleghani st.,karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Doctor naseri

Street address

North kargar

City

Tehran

Province

Tehran

Postal code

۴۴۳۱۵۵۶۷۳

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+98 21 8835 4471

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dr_yasha_fayaz@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Habolshafa capsules

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

Iran University of Medical Sciences

Full name of responsible person

Yasha fayaz faizy

Position

Phd candidate

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Yasha fayaz faizy
Position
Phd candidate
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

data will be published after making undetectable

When the data will become available and for how long

from 1402

To whom data/document is available

research center of universities

Under which criteria data/document could be used

data analysis allowed

From where data/document is obtainable

dr_yasha_fayaz@yahoo.com yasha fayaz faizy

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

after submitting email , the answer posted after about 30 days

Comments