

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Investigation of the Effectiveness of Mobile-Based Ecological Momentary Motivational Enhancement Intervention on the Reduction of Craving and Severity of Cannabis Use Disorder among the Youth: A Randomized Clinical Trial

Protocol summary

Study aim

Comparing the effectiveness of mobile-based ecological momentary MET with face-to-face MET on the reduction of craving and severity of cannabis use disorder

Design

This study is a randomized, parallel, single-blind clinical trial with two intervention (EM-MET) and control (MET) groups, which will be conducted in the first phase on 80 patients with cannabis use disorder. The random assignment of patients will be done using a simple randomization method using a random number table.

Settings and conduct

First, the main outcome variables will be evaluated in MET and EM-MET groups. Then, both groups will receive four face-to-face motivational enhancement therapy sessions. The MET group will not receive any other interventions after these sessions, while the EM-MET group will also receive mobile-based ecological momentary motivational enhancement therapy after face-to-face sessions in a three-week period. Six weeks after the end of this three-week period, the outcome variables in both groups will be evaluated in the follow-up.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Being diagnosed with cannabis use disorder based on DSM-5 criteria 2. Being aged 18-24 years 3. Using cannabis at least three times a week 4. Giving consent for participation in the study Exclusion criteria 1. Being dependent on other drugs simultaneously 2. Existence of severe psychotic symptoms based on DSM-5 criteria 3. Having received treatment for cannabis use disorder in the past 12 months

Intervention groups

The face-to-face MET group will receive four face-to-face sessions Mobile-based ecological momentary

motivational enhancement therapy group (EM-MET) will receive a mobile-based motivational intervention, if needed, in addition to four face-to-face sessions

Main outcome variables

The severity of craving and cannabis use disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056908N1**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Mohammad Darharaj

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effectiveness of Mobile-Based Ecological Momentary Motivational Enhancement Intervention on the Reduction of Craving and Severity of Cannabis Use Disorder among the Youth: A Randomized Clinical Trial

Public title

Effectiveness of Ecological Momentary Motivational Enhancement Intervention for the Treatment of Cannabis Use

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being diagnosed with cannabis use disorder based on DSM-5 diagnostic criteria Being aged 18-24 years old Using cannabis at least three times a week Giving consent for participation in this study

Exclusion criteria:

Being dependent on other drugs simultaneously Showing severe psychotic symptoms based on DSM-5 criteria Having received treatment for cannabis use disorder in the past 12 months Using Taking psychiatric drugs

Age

From **18 years** old to **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the simple randomization method will be used to randomly assign participants to the intervention groups. The randomization unit in this study will be a patient with a cannabis use disorder. In order to randomize the participants, a random numbers table will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single-blind study in which the statistical analyst is blinded to the intervention. To do so, in the data file that is provided for the statistical analyst, the treatment groups to be compared will be anonymous and will only be identified as groups A and B. Therefore, the statistical analyst will be unaware of the type of

intervention that each of these groups has received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Iran University of Medical Sciences

Street address

Department of Mental Health, School of Behavioral Sciences and Mental Health (Tehran Institute of Psychiatry), No. 1, Mansouri St., Niayesh St., Sattarkhan Blvd,

City

Tehran

Province

Tehran

Postal code

1445613111

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.IUMS.REC.1401.906

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

Cannabis Use Disorder

ICD-10 code

F12

ICD-10 code description

Cannabis related disorders

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

Cannabis Use Craving

Timepoint

Pretest, Post-test, Six-week Follow-up

Method of measurement

Drug Use Temptation Scale

2**Description**

Severity of Cannabis Use Disorder

Timepoint

Pretest, Post-test, Six-week Follow-up
Method of measurement
Leeds Dependence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mobile-Based Ecological Momentary Motivational Enhancement Intervention

Category

Behavior

2

Description

Control group: Face-to-face Motivational Enhancement Intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction treatment clinics of Iran, Tehran, and Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Darharaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahdi Amini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

Only some parts of the data such as information related to treatment outcomes can be shared.

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In case of conducting similar and additional research, the information of the current research will be accessible

From where data/document is obtainable

Contacting Mohammad Darharaj Darharaj.m@iums.ac.ir

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

Applicants are required to email their documents about conducting similar scientific research and after approval, they can access the information.

Comments