Clinical Trial Protocol
Iranian Registry of Clinical Trials
26 Sep 2023

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

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)
Phone
+98 21 5552 8921
Email address
darharaj.m@iums.ac.ir
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 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
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
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
Phone
+98 21 6655 1655
Email
Darharaj.m@iums.ac.ir

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Keyvani
Street address
No 10, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۵۳۵۴۱۶۹۴۴۱
Phone
+98 21 8670 2503
Email
Keyvani.h@iums.ac.ir
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
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
Phone
+98 21 6655 1655
Email
amini.mh@iums.ac.ir
Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Roshanpajouh
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Department of Mental Health, School of Behavioral Sciences and Mental Health (Tehran Institute of Psychiatry), No. 1, Mansouri St., Niyesh St., Sattarkhan Blvd
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
roshanpajouh@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mojtaba Habibi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Department of Mental Health, School of Behavioral Sciences and Mental Health (Tehran Institute of Psychiatry), No. 1, Mansouri St., Niyesh St., Sattarkhan Blvd
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
Habibi.m@iums.ac.ir

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