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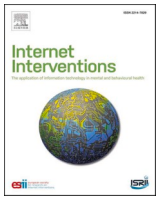

The effectiveness of mobile-based ecological momentary motivational enhancement therapy in reducing craving and severity of cannabis use disorder: Study protocol for a randomized controlled trial

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ABSTRACT

Objective: This study aims to investigate the effectiveness of Ecological Momentary Motivational Enhancement Therapy (EM-MET) in reducing craving and severity of Cannabis Use Disorder (CUD) among young adults.
Methods: This multicenter, single-blinded randomized controlled trial (RCT) will be conducted over a period of 11 weeks. Eighty patients with CUD will be randomly assigned to two equal-sized parallel groups, either the Motivational Enhancement Therapy (MET) group or the EM-MET group. All participants will receive four individual face-to-face sessions of MET (twice a week). The MET group will not receive any other treatments after these sessions; however, in the EM-MET group, the top triggers of patients will be assessed using mobile-based Ecological Momentary Assessment (EMA) five times a day within three weeks (after face-to-face sessions) and they will receive a call from the therapist who provides them with EM-MET (in the form of an emergency telephone helpline) as soon as they report experiencing triggers of cannabis use that are assessed using EMA in their everyday lives. Primary outcomes including CUD severity and the severity of craving will be evaluated using the Leeds Dependence Questionnaire and the Self-efficacy and Temptation Scale, respectively. These assessments will be conducted at pre-treatment, post-treatment, and a six-week follow-up.
Discussion: If proven feasible and effective, the results of this study will offer clinicians an evidence-based treatment approach to address craving and dependency in patients with CUD. Moreover, these patients will receive effective treatment in real time and in real life, when and where it is most needed. However, it is important to consider the limitations of this study, such as the specific population studied in Tehran, Iran, which may affect the generalizability of the results. Nevertheless, the implementation of Ecological Momentary Interventions (EMIs) in real-life settings holds promise for timely and effective treatment.
Trial registration: This trial was registered in the Iranian Registry of Clinical Trials on 21 February 2023. Registry No. IRCT20221224056908N1.

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1. Introduction

1.1. Background

Cannabis is the most commonly used drug worldwide; about 209 million people aged 15–64 years old used cannabis in 2020, showing a 23 % increase in the number of cannabis users in the past decade (United Nations Office on Drugs and Crime, 2022). Given reports indicating that about 9.9 % of people who use cannabis have Cannabis Use Disorder (CUD), >20 million people are affected by CUD, many of whom are young adults aged 18–24 (United Nations Office on Drugs and Crime, 2020). Similarly, epidemiological research conducted in Iran has also shown a relatively high lifetime prevalence of cannabis use, with estimations ranging from 9 % among adolescents (Hosseini et al., 2022) to 10.9 % among the general population aged 15–64 years old (Roshanpajouh et al., 2020). Although the 12-month prevalence of cannabis use among Iranian males (1.3 %) and females (0.2 %) is lower than that of many other countries, cannabis use among Iranians has also been on an upward trend in the past two decades (Rostam-Abadi et al., 2021).

Given the high prevalence of cannabis use among young adults and its repercussions including cognitive deficits (Bourque and Potvin, 2021), poor academic performance (Cyrus et al., 2021), and psychological disorders (Lowe et al., 2019), it is important to develop interventions to treat CUD in this age group. However, drug craving is one of the most critical issues that challenges therapeutic practices and causes continued drug use among cannabis users seeking treatment (Enkema et al., 2020). A behavioral component of addiction and a common problem among patients with CUD, craving refers to a strong and conscious desire toward the use of a specific drug (Tiffany and Wray, 2012). Existing evidence has indicated that cannabis users experience a high level of cue-elicited craving in response to cannabis-associated stimuli (Sehl et al., 2021), which in turn, increases the risk of relapse and exacerbates cannabis use-related consequences (Enkema et al., 2020). Therefore, addressing craving in the treatment of patients with CUD is particularly important.

In this regard, previous studies have shown the effectiveness of various psychotherapy approaches including but not limited to cognitive behavior therapy (Buckner et al., 2021), contingency management (Hirchak et al., 2022), and multidimensional family therapy (Goorden et al., 2016) in the treatment of CUD. Motivational Interviewing (MI; a brief client-centered approach designed to enhance motivation for behavioral changes) and Motivational Enhancement Therapy (MET; a kind of MI that includes personalized assessment, feedback, and change plans) (Miller and Rollnick, 2002) have also been shown to be effective treatments for patients with CUD (D'Amico et al., 2018). Indeed, there is evidence indicating that MET may be superior to other alternative treatments including but not limited to cognitive behavior therapy in reducing substance use (Lenz et al., 2016). In particular, a systematic review of 40 studies indicated that MI and MET are effective interventions that help both adults and adolescents with CUD to achieve abstinence (Calomarde-Gómez et al., 2021). However, some other studies have yielded inconsistent findings; for example, in their meta-analysis and systematic review, Li et al. (2016) concluded that MI has no significant effect on the change in drug use behaviors. Besides, the effects of MET may not be sustained after treatment (Shrier et al., 2018). Therefore, more research is needed into the effectiveness of MET on CUD as well as its provision in real-time, in daily life, to ensure the consistency of therapeutic effects.

Ecological Momentary Interventions (EMIs) are based on the Ecological Momentary Assessment (EMA) of patients and the delivery of therapeutic interventions to them in real-time when most needed (e.g., when patients experience an emotional state that triggers an unhealthy behavior such as drug use) and in daily life (Heron and Smyth, 2010). Such interventions that enhance the impact of clinic-based treatments have much effectiveness when combined with face-to-face treatments (Versluis et al., 2016). That is, in EMI, patients have this opportunity to practice newly-learned skills and behaviors between treatment sessions and in their everyday lives (Heron and Smyth, 2010).

Existing literature on mobile-based EMI has demonstrated its effectiveness in the reduction of tobacco use (Hébert et al., 2020), alcohol use (Leonard et al., 2017), generalized anxiety disorder (LaFreniere and Newman, 2016), depression (Burns et al., 2011), and unhealthy behaviors (Allicock et al., 2021). Some studies have also shown the effectiveness of EMI, particularly mobile-based ecological momentary MET, on the reduction of marijuana use among youths (Shrier et al., 2018; Shrier et al., 2014). However, their findings have some limitations that should be taken into account. Firstly, participants of these studies were marijuana users only, not patients with CUD; this is particularly important since these patients experience more severe problems due to their long-term and chronic cannabis use, which in turn, may undermine therapeutic effects. Secondly, some of these studies lack control groups (Shrier et al., 2014); given that using a control group allows researchers to confirm that study findings are the result of manipulating independent variables (Allen, 2017), lack of control group in these studies makes it difficult to come to significant conclusions. Thirdly, the small sample size of the previous studies limited power to detect intervention effects. Finally, although only a few of the previous studies on mobile-based EMIs have examined the effectiveness of such interventions on any intensity of desire to use marijuana (Shrier et al., 2018; Shrier et al., 2014), none of them has investigated the extent to which these interventions can decrease craving as a "*strong desire*" to take drugs (Kozlowski and Wilkinson, 1987) among patients with CUD. According to Marlatt's and Gordon's relapse prevention model (Marlatt and Gordon, 1985), craving is one of the most critical covert antecedents of relapse. Therefore, addressing drug cravings in the treatment of patients with CUD may prevent relapse (Enkema et al., 2020). We plan to conduct an RCT to examine the feasibility, acceptability, and effectiveness of a mobile-based ecological momentary MET on the reduction of craving and severity of CUD among young adults.

1.2. Objectives

1.2.1. Primary objective

The primary objective of this study is to investigate the feasibility and acceptability of a mobile-based Ecological Momentary Motivational Enhancement Therapy (EM-MET) for young adults with CUD.

1.2.2. Secondary objective

The key secondary objective is to determine if EM-MET is superior to MET in reducing craving and CUD severity among young adults, through an RCT with a six-week follow-up.

1.3. Hypotheses

Our primary hypothesis states that both EM-MET and MET will decrease craving and CUD severity among young adults using cannabis. Secondly, we hypothesize that there will be significant differences between these two groups, such that EM-MET will be significantly more effective than MET in decreasing the severity of craving and CUD among young adults.

2. Methods

2.1. Trial design

A multicenter single-blinded RCT with two equal-sized parallel groups will be conducted at three specialized substance abuse treatment centers in Iran, Tehran, and Shahid Beheshti Universities of Medical Sciences. Patients aged 18–24 years with CUD will be enrolled and randomized into two groups (MET vs. EM-MET) and assessed at pre-treatment, post-treatment, and six-week follow-up, resulting in a 2 (group) × 3 (time) repeated measures factorial design. An overview of

the proposed flow of participants is shown in Fig. 1.

2.2. Participants

We will enroll a total of 80 patients with CUD through a voluntary sampling method from three substance abuse treatment centers in Iran, Tehran, and Shahid Beheshti Universities of Medical Sciences. Eligibility criteria are (1) being diagnosed with CUD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnostic criteria, (2) being aged 18–24 years, (3) using cannabis at least three times a week, (4) having a mobile phone, and (5) giving consent to participate in this study. Patients will be excluded from the study if they are (1) dependent on other drugs except for nicotine, (2) diagnosed with severe psychotic symptoms based on DSM-5 criteria, or (3) using psychoactive drugs at the time of enrollment. A summary of inclusion and exclusion criteria has been demonstrated in Table 1.

Table 1
An overview of the inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Diagnosis of CUD according to the DSM-5	Simultaneous dependency on other drugs, except nicotine
Age of 18–24 years	
Cannabis use at least three times a week	Diagnosis of severe psychotic symptoms according to DSM-5
Ownership of a mobile phone	
Giving consent for participation	Using psychoactive drugs

2.3. Intervention

2.3.1. Motivational enhancement therapy (MET)

The MET that will be used in this study is adapted from a protocol developed and tested by Khaliliyan et al. (2020). This protocol, which

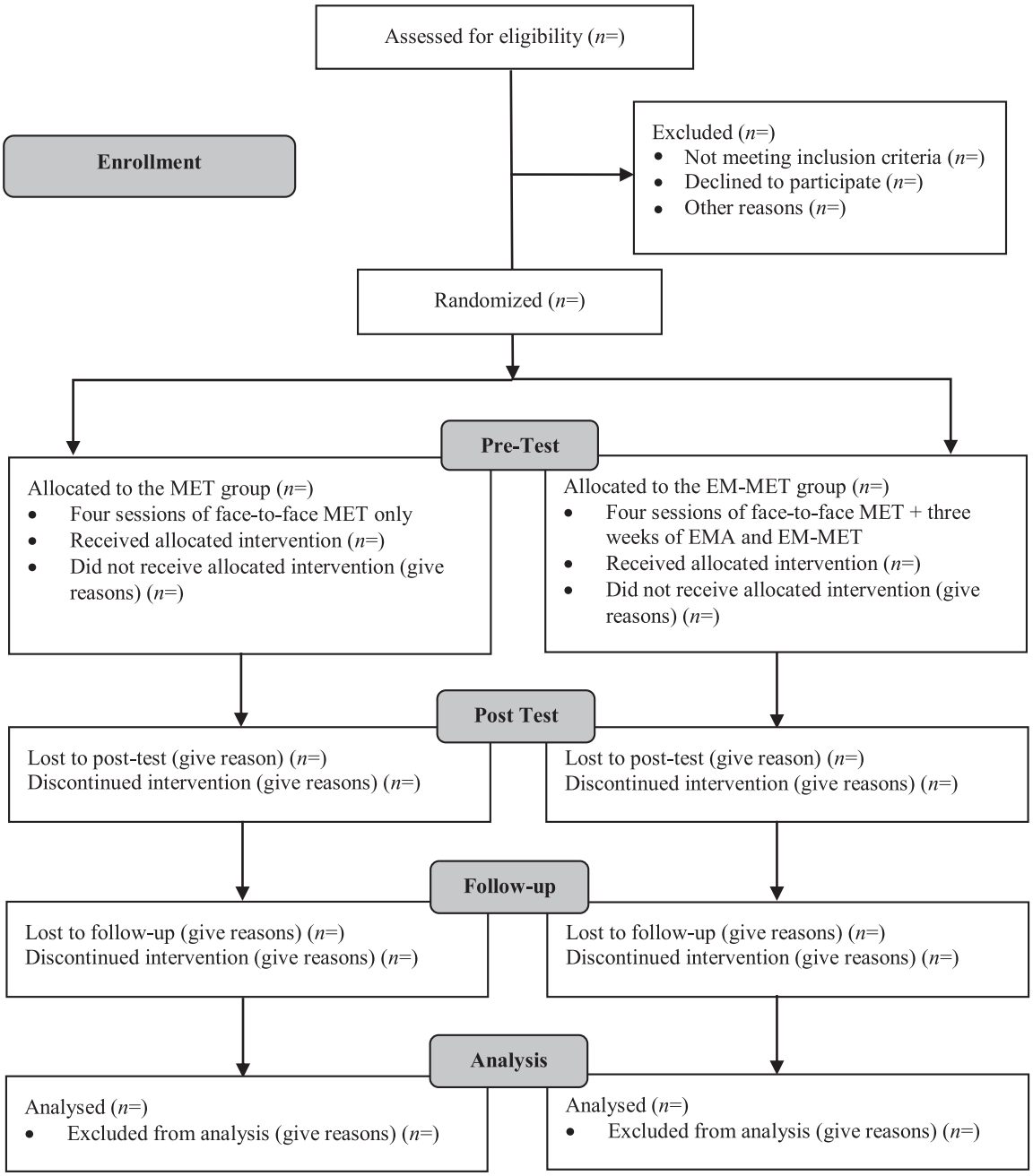

Fig. 1. Flow diagram of the progress through the phases of a 2-group parallel randomized trial flow.

has already been shown to be effective for Iranian patients with substance use disorder, provides patients with four individual 90-min sessions (twice a week) and includes components such as 1) raising the awareness of patients about the extent and severity of the cannabis use problem, 2) eliciting clients' goals and values, 3) creating and amplifying patients' discrepancy, 4) evoking patients' motivation for reducing or abstaining from cannabis, and 5) developing a change plan. Table 2 shows the outline of the MET sessions.

2.3.2. Ecological momentary motivational enhancement therapy (EM-MET)

The content of the mobile-based EM-MET is the same as that of the MET, and they only differ from each other in the way that they are provided. The MET is delivered in face-to-face sessions in clinics. The EM-MET is delivered momentarily using a mobile phone. In other words, for three weeks, the top triggers of cannabis use for each patient will be assessed in real-time using a short messaging service application programming interface (SMS API). If patients report experiencing one of these triggers, they will immediately receive a real-time call from the therapist who provides them with ecological momentary MET in the form of mobile-delivered psychotherapy to deal with the situation and the trigger.

2.4. Feasibility and acceptability measures

The dropout rate (i.e., the percentage of participants who drop out of the treatment), engagement rate (i.e., the percentage of participants who respond to the text messages sent for EMA of triggers), and response rate (i.e., the percentage of patients who answer the therapist's call to receive the counseling) will be calculated to examine the feasibility of the mobile-based EM-MET for young adults with CUD. Moreover, to investigate the acceptability of the mobile-based EM-MET, two indices will be calculated; firstly, participants' satisfaction with the treatment will be measured using a single item (i.e., "*In general, how much were you satisfied with the mobile-based EM-MET?*") that is scored on a 7-point Likert scale ranging from 1 ("*Totally dissatisfied*") to 7 ("*Totally satisfied*"). Secondly, the usefulness of the treatment will also be examined using a single question (i.e., "*In general, how useful did you find the mobile-based EM-MET?*"); answers to this question will also be rated on a 7-point Likert scale from 1 ("*Totally useless*") to 7 ("*Totally useful*").

2.5. Selection measures

2.5.1. Structured clinical interview for DSM (SCID)

CUD will be diagnosed by the SCID, which is a clinician-administered instrument for the classification of psychiatric disorders based on the DSM-5 diagnostic criteria (First et al., 1996). This interview provides clinicians with highly reliable diagnoses for psychiatric disorders and, therefore, it is the most commonly used semi-structured interview in research and clinical practices. Examining the psychometric properties of the SCID has indicated its good inter-rater reliability (kappa coefficient = 0.60) (Tran and Smith, 2004). The Persian version of the SCID that will be used in this study has also been standardized; investigation of the psychometrics of this version has shown that the diagnostic agreement for most of the diagnostic categories was satisfactory (kappa coefficient > 0.60) (Sharifi et al., 2004). Therefore, the SCID is a reliable instrument applicable to Iranian psychiatric patients.

Table 2
Outline of Motivational Enhancement Therapy for cannabis use disorder.

Session	Agenda
One	Introducing the MET, describing the results of the STS and LDQ to clients, determining triggers of cannabis use, providing information about the consequences of cannabis use, and describing a typical day of cannabis use
Two	Reviewing the previous session, working on clients' ambivalence, evoking clients' goals and values using personal goals and values card sorting task, and creating and amplifying clients' discrepancy
Three	Reviewing the previous session, using a motivation ruler to direct clients toward change talk, normalizing ambivalence and concerns, and developing a change plan in collaboration with clients
Four	Reviewing the client's situation and progress through the MET, exploring related areas of change, emphasizing the client's ability to change, and reminding the client of follow-up sessions

2.6. Momentary-level measures

Two cannabis use-related measures will be assessed at the momentary level including the desire to use cannabis (i.e., *"At the time of receiving notification, how strong was your desire to use cannabis?"*, with response options ranging from 0 = *No desire* to 9 = *Strong desire*) and cannabis use (i.e., *"Since the last notification you received, have you used cannabis?"*, with response options including 0 = *No* and 1 = *Yes*). Adapted from Shrier et al. (2014), the top triggers of cannabis use that will be measured at the momentary level also include patients' emotional status and social contexts (i.e., location, companionship, and main activity). In face-to-face sessions, participants will be asked to select their top triggers from a list of triggers first. More specifically, to identify a participant's top emotional trigger in this list, he/she will be asked, "*When experiencing what feeling are you most likely to use marijuana?*"; the response options include each of the affective states measured by the Positive and Negative Affect Schedule (PANAS) (Watson et al., 1988). To identify the top social contexts that trigger cannabis use, patients will also be asked "*Where are you most likely to use marijuana?*" (i.e., location, with response options including at work, at a friend's house, at a relative's house, etc.), "*When being with whom are you most likely to use marijuana?*" (i.e., companionship, with response options including with family, with friends, etc.), and "*When doing what are you most likely to use marijuana?*' (i.e., main activity, with response options including hanging out, resting, being intimate, etc.). Having identified top triggers, text messages that include questions assessing these triggers will be sent to the participants five times a day and their top triggers will be measured momentarily. For example, a patient who reports being anxious, being at a friend's house, being with friends, and hanging out as his/her top triggers of cannabis use will receive five messages a day that asks him/ her "*How anxious are you now?*" (response options ranging from 1 = *Very slightly or not at all* to 5 = *Extremely*), "*Are you at your friend's house now?*" (response options 0 = *No* and 1 = *Yes*), "*Are you with your friend now?*" (response options 0 = *No* and 1 = *Yes*), "*Are you hanging out now?*" (response options 0 = *No* and 1 = *Yes*).

2.7. Outcome measures

2.7.1. Leeds dependence questionnaire (LDQ)

In this study, the LDQ (Raistrick et al., 1994) will be used to measure the severity of CUD. This is a self-report 10-item questionnaire that measures mild to severe substance dependence. The items are scored on a four-point Likert scale ranging from 0 ("*Never*") to 3 ("*Nearly always*"); therefore, the total score ranges from 0 to 30, with higher scores demonstrating more severe dependence on drugs. Examining the psychometric properties of the LDQ has shown its excellent internal consistency (α = 0.94), test-retest reliability (r = 0.95), and validity (Raistrick et al., 1994). The Persian version of the LDQ that will be used in this study has also been examined in a sample of Iranian patients with substance use disorder, with results showing its great internal consistency (α = 0.90). Moreover, the significant positive relationship between the Persian version of the LDQ and the Severity of Dependence Scale (SDS) (Gossop et al., 1995) supports convergent validity of the LDQ among Iranians (Habibi et al., 2016).

2.7.2. Self-efficacy and temptation scale (STS)

In this study, the STS (Hiller et al., 2000) will be utilized for the assessment of craving in patients with CUD. The STS, which was adapted from Alcohol Abstinence Self-Efficacy Scale (DiClemente et al., 1994), is

a self-report instrument that measures both self-efficacy and temptation of drug abusers in 20 high-risk situations in four conceptual categories including negative affect, social/ positive, physical concerns, and cravings/ urges. Given that response to these items is scored on a five-point Likert scale with anchors of 1 ("*Not at all*") and 5 ("*Extremely*"), the total score for each of the subscales ranges from 20 to 100, with the higher score showing a higher level of self-efficacy and temptation. Hiller et al. (2000) reported satisfactory internal consistency and construct validity of the STS in a mixed sample of cocaine, alcohol, cannabis, and other illicit drug users. The Persian version of the STS that will be utilized in the current study has already been translated and validated in a sample of Iranians with drug use disorder, with results indicating high internal consistency (Cronbach alphas ranged from 0.82 for "*physical concerns*" to 0.89 for "*cravings/urges*") and validity for the temptation subscale (Asli Khalan et al., 2020). Table 3 shows an overview of study assessments.

2.8. Sample size

G*Power software will be used to calculate the sample size of this study. In an a priori power analysis, we assumed that the smallest clinically relevant difference will be a small effect size of Cohen's $d = 0.20$ and smaller effect sizes will be of little clinical value (Lopes et al., 2021). Therefore, considering the number of dependent variables and times that participants will be assessed (i.e., three times in pre-intervention, post-intervention, and six-week follow-up), sample sizes will be 32 per condition (alpha = 0.05, effect size = 0.20, power = 0.95). Taking a 20 % drop-out into account, the final sample size of this study will include 80 young adults with CUD who will be randomly assigned to MET ($n = 40$) or EM-MET ($n = 40$).

2.9. Randomization

Using a computer-generated random number list, an independent statistician will randomly assign eligible participants to receive either MET or EM-MET. These patients will be randomly assigned in a 1:1 ratio with a permuted block size of four and sequential assignment, stratified by treatment center. The allocation concealment will be guaranteed; that is, the arm allocation and randomized sequence list will be concealed from the research team until the end of the registration period.

2.10. Blinding

Given the nature of psychotherapies provided for patients with CUD in this study, neither the psychotherapists nor the participants can be blinded to group assignment. Therefore, this is a single-blinded RCT in which the data analyst will be the only person blinded to the interventions. A data analyst will be asked to conduct data analysis, and he/she will not be given the codes for treatment group status.

2.11. Procedure

To conduct this study, ethical approval was received from the research ethics committee of the Iran University of Medical Sciences first (No. IR.IUMS.REC.1401.906). Patients newly admitted to substance abuse treatment centers in Iran, Tehran, and Shahid Beheshti Universities of Medical Sciences will be interviewed for inclusion and exclusion criteria and those who give written consent for their participation will be enrolled. These patients will be randomly assigned to the MET ($n = 40$) or EM-MET group ($n = 40$) and then, their craving (using STS) and severity of CUD (using LDQ) will be examined at pre-intervention.

In the intervention phase, participants in both groups will receive four individual face-to-face sessions of MET (twice a week) that are provided by a clinical psychologist who is experienced in substance abuse treatment and particularly, MET. During the first session, participants will select their top triggers for cannabis use, one each from lists of emotional states (e.g., anxious, happy, angry, etc.), companions (e.g., alone, with friends, with family, etc.), locations (e.g., at home, at work, etc.), and main activities (e.g., hanging out, resting, etc.). The MET group will not receive any other treatment after these sessions.

For participants in the EM-MET group, their top triggers will be assessed using mobile-based EMA five times a day for the three weeks after the last face-to-face MET session. The EMA will be conducted by SMS API text messages sent to the participants at random times during waking hours. The participants will be able to respond to these text messages via SMS and report their top triggers (if any). Participants who endorse one of their top triggers will receive a call from the therapist, who provides them with EM-MET (in the form of an emergency telephone helpline). If the participant does not respond to the therapist's call, two more calls will be made with the patient at an interval of 15 min each, and if he/she still does not respond to any of these calls, a text message with motivational content will be sent to him/her. Participants will also be able to use the SMS API to inform the therapist about the triggers they are experiencing or any other urgent concerns requiring immediate response from the therapist. Five research assistants will receive and check participants' responses to text messages to make real-time monitoring of these responses feasible. In addition, given that several patients may need to receive EM-MET simultaneously, four psychotherapists will be recruited to provide these patients with the intervention. In this case, to make sure of treatment fidelity, all the participating therapists will receive training first and then, they will provide patients with EM-MET in this RCT. To ensure these therapists' fidelity to the treatment protocol, voice recordings of their calls will be monitored by a supervising clinical psychologist and (if necessary) they will receive corrective feedback.

Severity of craving and of CUD will be examined in both EM-MET and MET groups at three weeks after the four MET sessions, which will be immediately after the mobile-based MET for participants in the EM-MET group, and then in the six-week follow-up. All participating patients will be offered compensation for remuneration of up to $20 in gift cards, depending on the proportion of study activities completed.

Table 3
Overview of study assessments.

Feasibility and acceptability measures	Dropout /response rate, satisfaction, and usefulness
Selection measures	Diagnosis of SUD based on SCID
Momentary-level measures	Desire to use cannabis, recent cannabis use, and personal triggers for cannabis use
Outcome measures	Severity of craving and CUD assessed by STS and LDQ

2.12. Data analysis

All data analyses will be conducted on an intent-to-treat (ITT) principle, including data for each participant who is randomized. Using multiple imputation, patterns of missing data will be examined and analyses will be corrected for missing. Descriptive statistics including means and standard deviations will be reported for both groups in three measurement stages including pre-intervention, post-intervention, and follow-up. Then, linear mixed-effects models, incorporating both between-subject and within-subject factors, will be utilized to examine the effectiveness of the intervention on continuous outcome variables over time. Assessment time points (i.e., pre-treatment, post-treatment, six-week follow-up), condition (i.e., MET, EM-MET) and the interaction of time-by-condition will be specified as categorical fixed factors. Given studies indicating the effect of known demographic variables such as gender (Hitschfeld et al., 2015) and education (PoorSeyedMousaiee et al., 2015) on drug cravings, these variables will be considered as covariates. Also, to examine the effectiveness of the intervention, the statistical indices of the effect size (including Eta squared and Cohen d) will be calculated. In addition, this study will utilize the Reliable Change Index (RCI) (Jacobson and Truax, 1991) to examine the magnitude of change and investigate clinically significant differences in the severity of

craving and CUD before and after MET. Data analysis will be conducted using Stata 18.

3. Discussion

Patients with CUD often experience a high level of craving which makes them vulnerable to relapse. Although different treatment approaches including MET are effective for cannabis use-related problems (D'Amico et al., 2018; Calomarde-Gómez et al., 2021), the momentary nature of craving necessitates extending these treatment practices beyond face-to-face sessions to daily life environments. Therefore, this study was planned to examine the feasibility and effectiveness of a mobile-based EM-MET to address the severity of craving and of CUD among young adults in real time and in their daily life contexts.

3.1. Clinical implications

If proven feasible and effective, our findings will help clinicians to administer an evidence-based treatment to address craving and dependence in their patients with CUD. Furthermore, the results of this study will provide these patients with a more accessible treatment in real-time when most needed. Therefore, not only do such treatments decrease the costs of receiving therapeutic interventions, but also, they may help patients with CUD to adhere more strictly to treatment beyond face-to-face sessions in the clinics and therefore, reduce the rate of relapse in these patients.

3.2. Limitations

The foreseen limitations of this study are the following. First, given studies indicating that only a minority of those diagnosed with CUD seek treatment (Khan et al., 2013), recruiting 80 cannabis users with specific aforementioned inclusion and exclusion criteria may be challenging. To overcome this limitation, participants will be recruited from several substance abuse treatment centers. Second, due to the number of EMA messages (i.e., five times a day), there may be a higher-than-expected dropout rate in the EM-MET group. This limitation will be addressed by paying patients for their study participation. Moreover, in the case of high dropout, as mentioned, multiple imputations will be used to address missing data. Third, our sample includes a specific population in Tehran, Iran, and those patients who have access to a mobile phone, which limits the generalizability of the study to other populations and to individuals without cell phones. Lastly, the relatively short follow-up period limits the inferences that can be preliminarily drawn about the long-term effects of the intervention. Future efficacy studies will extend the duration of the follow-up.

Consent to participate

Informed consent will be taken from all participants.

CRediT authorship contribution statement

Mohammad Darharaj: concept of the paper, literature review, sharing in writing the manuscript, and revision of the manuscript. Mohsen Roshanpajouh: study conception and revision of the manuscript. Mahdi Amini: study conception and design. Lydia A. Shrier: drafting of the manuscript and grammatical revisions. Mojtaba Habibi Asgarabad: study design and drafting of the manuscript. Authors are responsible for correctness of the statements provided in the manuscript. The author(s) read and approved the final manuscript.

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Ethics approval and consent to participate

All methods were carried out in accordance with relevant guidelines. This study was approved by the Ethics Committee of the Iran University of Medical Sciences (IR.IUMS.REC.1401.906). The informed consent form will be prepared according to the standards of the Ethics Committee of Iran University of Medical Sciences and will be obtained from all participants. Also, all patients will be informed about the interventions before signing the consent form. Finally, all patients' data will be archived confidentially.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The final trial dataset will be accessible by sending an email to the corresponding authors.

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Not applicable.

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