

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The efficacy of cue exposure therapy on treatment outcome of stimulant use disorder

#### Protocol summary

##### Study aim

1- efficacy of cue exposure therapy on craving reduction of patients with stimulant use disorder in comparison with control group. 2- efficacy of cue exposure therapy on reduction of addiction severity in patients with stimulant use disorder in comparison with control group. 3- efficacy of cue exposure therapy on relapse prevention in patients with stimulant use disorder in comparison with control group. 4- efficacy of cue exposure therapy on enhancement of quality of life in patients with stimulant use disorder in comparison with control group.

##### Design

this is a randomized control trial with control group and follow up. sample size is 40, participants will be allocated randomly into two groups with using statistical software

##### Settings and conduct

this study will be held in Iranian national center of addiction study. participants are blind about random allocation

##### Participants/Inclusion and exclusion criteria

inclusion criteria: patients with stimulant use disorder diagnosis, having at least 18 years old, not using any kind of drug except of nicotine within 2 weeks before program starting, ability of reading and writing Persian language, completion of informed consent form.

exclusion criteria: if patient has severe physical illness, psychotic symptoms or suicidal ideations will be excluded from program.

##### Intervention groups

cue exposure therapy (CET) and treatment as usual (TAU)

##### Main outcome variables

primary outcome is: drug use reduction secondary outcomes include: craving, self efficacy, addiction severity, quality of life and depression, anxiety and stress severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180218038782N1**

Registration date: **2018-09-09, 1397/06/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-09, 1397/06/18**

Update count: **0**

##### Registration date

2018-09-09, 1397/06/18

##### Registrant information

##### Name

Meghdad Talebizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6655 1515

##### Email address

talebizadeh.m@tak.iuums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-09-06, 1397/06/15

##### Expected recruitment end date

2018-11-06, 1397/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of cue exposure therapy on treatment outcome of stimulant use disorder

#### Public title

The efficacy of cue exposure therapy on treatment outcome of stimulant use disorder

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

stimulant use disorder diagnosis not using any kind of drug except of nicotine within two weeks before program starting Ability of reading and writing persian language Completion of informed consent form

##### Exclusion criteria:

having sever suicidal ideation having psychotic symptoms having acute physical problems

#### Age

From **18 years** old to **64 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

simple randomization by app or websites

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

patients will not get any informations about assignment process

#### Placebo

Not used

#### Assignment

Factorial

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran univeristy of medical sciences

##### Street address

Deputy of research and technology, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,IRAN.

##### City

Tehran

##### Province

Tehran

#### Postal code

1449614535

#### Approval date

2018-03-18, 1396/12/27

#### Ethics committee reference number

9221521204

## Health conditions studied

### 1

#### Description of health condition studied

stimulant use disorder

#### ICD-10 code

F15.2

#### ICD-10 code description

Other stimulant dependence

## Primary outcomes

### 1

#### Description

treatment outcome includes: addiction severity, craving, relapse rate, quality of life and severity of depression, anxiety and stress that will be measured by addiction severity index (ASI), Desires for Drug Questionnaire (DDQ), Obsessive Compulsive Drug Use Scale (OCDUS), urine test, World Health Organization Quality of Life-Brief (WHOQOL-BREF) and Depression Anxiety Stress Scales (DASS-21).

#### Timepoint

assessment will complete at pre-test, post-test and follow up (3 months after treatment completion)

#### Method of measurement

addiction severity index (ASI), Desires for Drug Questionnaire (DDQ), Obsessive Compulsive Drug Use Scale (OCDUS), urine test, World Health Organization Quality of Life-Brief (WHOQOL-BREF) and Depression Anxiety Stress Scales (DASS-21).

## Secondary outcomes

### 1

#### Description

addiction severity

#### Timepoint

pretest, post test, 3 months follow up

#### Method of measurement

addiction severity index (ASI)

### 2

#### Description

craving

#### Timepoint

pretest, post test, 3 months follow up

#### Method of measurement

Desires for Drug Questionnaire (DDQ) and Obsessive Compulsive Drug Use Scale (OCDUS).

### 3

**Description**

relapse rate

**Timepoint**

pretest, post test, 3 months follow up

**Method of measurement**

urine test

### 4

**Description**

quality of life

**Timepoint**

pretest, post test, 3 months follow up

**Method of measurement**

World Health Organization Quality of Life-Brief (WHOQOL-BREF)

### 5

**Description**

severity of depression, anxiety and stress

**Timepoint**

pretest, post test, 3 months follow up

**Method of measurement**

Depression Anxiety Stress Scales (DASS-21)

## Intervention groups

### 1

**Description**

Intervention group: cue exposure treatment

**Category**

Behavior

### 2

**Description**

Control group: treatment as usual (TAU)

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Iranian National Center for Addiction Studies

**Full name of responsible person**

Alireza Noroozi

**Street address**

No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital

**City**

Tehran

**Province**

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**Postal code**

1111111111

**Phone**

+98 21 5541 5225

**Email**

talebizadeh.m86@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

dr kazem malakouti

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN.

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**Phone**

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**Email**

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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**

Meghdad Talebizadeh

**Position**

Ph.D. candidate

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No 1. Tehran Psychiatric Institute, School of Behavioral Sciences and Mental Health, mansouri ave, Niayesh st. satarkhan st. tehran

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

all of data will be available with regard to confidentiality principle

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

only for researchers

**Under which criteria data/document could be used**

those researchers interested to re analysis or doing meta analysis can request for receiving data

**From where data/document is obtainable**

to get data they should send a request to email address of Talebizadeh: talebizadeh.m86@gmail.com

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

researchers should note why they need data files and how they are going to use them.

**Comments**