

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 exert 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 |                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Public title</b>                                                                 | The efficacy of cue exposure therapy on treatment outcome of stimulant use disorder                                                                                                                                                                                                                                                                             |
| <b>Purpose</b>                                                                      | Education/Guidance                                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>                                                 | <b>Inclusion criteria:</b><br>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 <b>Exclusion criteria:</b><br>having sever suicidal ideation having psychotic symptoms having acute physical problems |
| <b>Age</b>                                                                          | From <b>18 years</b> old to <b>64 years</b> old                                                                                                                                                                                                                                                                                                                 |
| <b>Gender</b>                                                                       | Male                                                                                                                                                                                                                                                                                                                                                            |
| <b>Phase</b>                                                                        | N/A                                                                                                                                                                                                                                                                                                                                                             |
| <b>Groups that have been masked</b>                                                 | <ul style="list-style-type: none"> <li>Participant</li> </ul>                                                                                                                                                                                                                                                                                                   |
| <b>Sample size</b>                                                                  | Target sample size: <b>40</b>                                                                                                                                                                                                                                                                                                                                   |
| <b>Randomization (investigator's opinion)</b>                                       | Randomized                                                                                                                                                                                                                                                                                                                                                      |
| <b>Randomization description</b>                                                    | simple randomization by app or websites                                                                                                                                                                                                                                                                                                                         |
| <b>Blinding (investigator's opinion)</b>                                            | Single blinded                                                                                                                                                                                                                                                                                                                                                  |
| <b>Blinding description</b>                                                         | patients will not get any informations about assignment process                                                                                                                                                                                                                                                                                                 |
| <b>Placebo</b>                                                                      | Not used                                                                                                                                                                                                                                                                                                                                                        |
| <b>Assignment</b>                                                                   | Factorial                                                                                                                                                                                                                                                                                                                                                       |
| <b>Other design features</b>                                                        |                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Secondary Ids</b>                                                                | empty                                                                                                                                                                                                                                                                                                                                                           |
| <b>Ethics committees</b>                                                            |                                                                                                                                                                                                                                                                                                                                                                 |
| <b><u>1</u></b>                                                                     |                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Ethics committee</b>                                                             |                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Name of ethics committee</b>                                                     | Ethics committee of Iran univeristy of medical sciences                                                                                                                                                                                                                                                                                                         |
| <b>Street address</b>                                                               | Deputy of research and technology, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,IRAN.                                                                                                                                                                                                                                                     |
| <b>City</b>                                                                         | Tehran                                                                                                                                                                                                                                                                                                                                                          |
| <b>Province</b>                                                                     | Tehran                                                                                                                                                                                                                                                                                                                                                          |

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Postal code</b>                             | 1449614535                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Approval date</b>                           | 2018-03-18, 1396/12/27                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Ethics committee reference number</b>       | 9221521204                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Health conditions studied</b>               |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Description of health condition studied</b> | stimulant use disorder                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>ICD-10 code</b>                             | F15.2                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>ICD-10 code description</b>                 | Other stimulant dependence                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Primary outcomes</b>                        |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Description</b>                             | 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). |
| <b>Timepoint</b>                               | assessment will complete at pre-test, post-test and follow up (3 months after treatment completion)                                                                                                                                                                                                                                                                                                         |
| <b>Method of measurement</b>                   | 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).                                                                                                                                                                |
| <b>Secondary outcomes</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Description</b>                             | addiction severity                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Timepoint</b>                               | pretest, post test, 3 months follow up                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Method of measurement</b>                   | addiction severity index (ASI)                                                                                                                                                                                                                                                                                                                                                                              |
| <b><u>2</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Description</b>                             | craving                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Timepoint</b>                               | pretest, post test, 3 months follow up                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Method of measurement</b>                   | 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

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## Sponsors / Funding sources

### 1

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

Iran University of Medical Sciences

**Full name of responsible person**

dr kazem malakouti

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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**

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## Person responsible for scientific inquiries

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**Latest degree**  
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**Other areas of specialty/work**  
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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**