

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

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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	stimulant use disorder
ICD-10 code	F15.2
ICD-10 code description	Other stimulant dependence
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
Description	addiction severity
Timepoint	pretest, post test, 3 months follow up
Method of measurement	addiction severity index (ASI)
<u>2</u>	
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

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

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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

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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

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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