

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

Tehran

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.

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6655 1668

Email

talebizadeh.m86@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

talebizadeh.m86@gmail.com

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

talebizadeh.m86@gmail.com

Person responsible for updating data

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

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1655

Email

talebizadeh.m86@gmail.com

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