

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of web-based interventions on the relapse rate of Methamphetamine use disorder at Iran psychiatric hospital

Protocol summary

Study aim

Investigating the effect of Matrix psychotherapy along with a web-based treatment program on the relapse rate of patients with methamphetamine use disorder

Design

Clinical trial with control group, with parallel groups, double-blind, randomized. The method of randomization will be done by Excel software.

Settings and conduct

The place of implementation is Iran Psychiatric Hospital. Samples randomly in two groups; The group treated with matrix and web-based programs (N=30); And the group treated with matrix alone(N=30)

Participants/Inclusion and exclusion criteria

Being 18-50 years old, having the criteria of methamphetamine dependence according to DSM V, not being treated with other drugs affecting craving, the patient's desire and predicting that the patient may attend will have the study, access to a mobile phone, no simultaneous use of drugs and alcohol except for cigarettes

Intervention groups

30 patients in the first group will receive matrix psychotherapy along with web-based follow-up during 4 months (once a month); 30 patients in the second group will receive only matrix psychotherapy during 4 months (once every month).

Main outcome variables

The relapse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056615N1**

Registration date: **2023-11-30, 1402/09/09**

Registration timing: **prospective**

Last update: **2023-11-30, 1402/09/09**

Update count: **0**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

Neda Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

vahed.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of web-based interventions on the relapse rate of Methamphetamine use disorder at Iran psychiatric hospital

Public title

The effect of web-based interventions on the relapse rate of Methamphetamine use disorder at Iran psychiatric hospital

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being between 18 and 50 years old Participants must meet the criteria for methamphetamine dependence according to DSM-V The patient's desire and predicting that the patient will be able to participate in the study (including taking into account the distance and hours required for the patient to attend the treatment center) Having access to a mobile phone

Exclusion criteria:

Taking other drugs that affect cravings (including modafinil, bupropion, naltrexone, N-acetylcysteine) Simultaneous consumption of other substances and alcohol except cigarettes Having severe psychiatric disorders

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Excel software will be used to generate a random sequence. Randomization will be done using blocks of 4 with two groups (experimental and control).

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluator and statistical analyzer will not know the type of patient group, all evaluations will be done by code

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

14665-354

Approval date

2023-07-14, 1402/04/23

Ethics committee reference number

IR.IUMS.REC.1402.352

Health conditions studied

1

Description of health condition studied

Patients with methamphetamine use disorder

ICD-10 code

F15

ICD-10 code description

Other stimulant related disorders

Primary outcomes

1

Description

Craving Score in Craving questionnaire

Timepoint

Before the intervention and once a month (up to 4 months)

Method of measurement

Obsessive Compulsive Drug Use Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to the matrix method, the intervention group will have face-to-face visits for psychotherapy every 4 weeks (depending on the patient's general condition and accompanying disorders, the patient may return earlier) and every 2 days they receive SMS and audio files with educational, motivational content and reminders of meeting times. The psychologists of the group will be in contact with the intervention group and the patient's family continuously and once a week by telephone. A patient who is a member of the intervention group, in case of encountering environmental triggers for relapse, informs the psychologist about the problem by sending a text message, and the therapist calls him immediately. The total intervention time will be 4 months

Category

Treatment - Other

2

Description

Control group: According to the matrix method, the control group will have a face-to-face visit for psychotherapy every 4 weeks (depending on the patient's general condition and associated disorders, the patient may return earlier). The whole treatment process will be up to 4 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatry Hospital

Full name of responsible person

Neda Vahed

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Azadegan ring road., 6th km of Karaj Makhsoos road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Reza Falak

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Adminsite@iums.ac.ir

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

Neda Vahed

Position

Research fellow

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Outcomes after the intervention

When the data will become available and for how long

2024

To whom data/document is available

Researchers

Under which criteria data/document could be used

Researchers from all scientific centers

From where data/document is obtainable

Email: vahedneda@yahoo.com

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

The email of the requester for data/documents will be answered within 3 weeks

Comments