

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effects of motivational interviewing on beliefs related to substances, craving and desire for treatment in methamphetamine-dependent psychotic patients

Protocol summary

Study aim

Evaluation of the effects of motivational interviewing on beliefs related to substances, craving and desire for treatment in methamphetamine-dependent psychotic patients

Design

Clinical trial with control group, randomized, phase 2 on 32 patients. Block randomization in blocks of 4 is used for randomization

Settings and conduct

An intervention group and a control group are both included in this investigation. In this study, patients admitted to Amirkabir Hospital's psychiatric ward with a clinical diagnosis of psychosis brought on by methamphetamine use according to DSM 5 criteria will be purposely chosen and randomly divided into two groups. This study will not use blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: DSM-5-based clinical diagnosis of methamphetamine-induced psychosis Occurrence of psychotic symptoms is up to one month after consumption Exclusion criteria: Restless and aggressive patients or with other symptoms interfering with treatment

Intervention groups

In both groups, patients filled out three questionnaires before starting the study, including: the questionnaire of beliefs related to drug and stages of readiness for change and enthusiasm for addiction treatment and also a measuring the temptation to use drugs after quitting and patients in the intervention group will participate in a 50-minute motivational interviewing session, and then, one week later, these three questionnaires will be provided to them to complete again. The information collected from these three questionnaires, which were filled out by both groups in both before and after the therapeutic intervention, would then be compared

Main outcome variables

beliefs related to substances Craving desire for treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056234N1**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Fatemeh Solhmirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of motivational interviewing on beliefs related to substances, craving and desire for treatment in methamphetamine-dependent psychotic patients

Public title

the effects of motivational interviewing on beliefs related to substances, craving and desire for treatment in methamphetamine-dependent psychotic patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

DSM-5-based clinical diagnosis of methamphetamine-induced psychosis . Occurrence of psychotic symptoms is up to one month after consumption.

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, we will use the restricted randomization method of the block randomization type. The number of samples assigned to each of the studied groups is equal. The size of all the blocks is equal and we will have 4 blocks in this two-group trial (including 2 participants in the intervention group and 2 participants in the control group). The randomization tool is also from the Random Allocation software. software is used that these random sequence generation softwares are capable of generating random sequence by block method in addition to simple randomization. In this method, each of the generated random sequences is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of the registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Shahid Shiroudi St., Nurse Square., Amirkabir Arak Hospital

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Postal code

3819693181

Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.ARAKMU.REC.1401.169

Health conditions studied**1****Description of health condition studied**

motivational interview

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

beliefs related to substances

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

craving

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

desire for treatment

ICD-10 code**ICD-10 code description****5****Description of health condition studied**

methamphetamine-dependent psychotic
ICD-10 code
F19.15
ICD-10 code description
Other psychoactive substance abuse with psychoactive
substance-induced psychotic disorder

Primary outcomes

1

Description

The score of beliefs related to substances in the Beck and Wright questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and 7 days after the motivational interview

Method of measurement

Beck and Wright questionnaire

2

Description

The score of the questionnaire measuring the craving to use substances after leaving Federdi, Bararfan and Ziyai

Timepoint

At the beginning of the study (before the start of the intervention) and 7 days after the motivational interview

Method of measurement

questionnaire measuring the craving to use substances after leaving Federdi, Bararfan and Ziyai

3

Description

The score of Miller and Tunigan stages of preparation for change and enthusiasm for addiction treatment questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and 7 days after the motivational interview

Method of measurement

Questionnaire stages of preparation for change and enthusiasm for addiction treatment by Miller and Tunigan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: single 50-minute motivational interview session

Category

Other

2

Description

Control group: Nothing is done

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Fatemeh Solhmirzaei

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Shahid Shiroudi St., Nurse Square ., Amirkabir Arak Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Solhmirzaei

Position

Intern

Latest degree

A Level or less

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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available