

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of the "lapse management" training on craving, relapse risk and abstinence self-efficacy of substances in people undergoing methadone maintenance treatment.

Protocol summary

Study aim

The effect of the "lapse management" training on craving, relapse risk and abstinence self-efficacy of substances in people undergoing methadone maintenance treatment.

Design

A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

The study population consisted of 76 addicts treated with methadone prescription drug referring to Imam Reza No.1- 4 addiction treatment centers in Birjand in 1396-97.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individual's willingness to participate in the study, male, age 18-50 years, referred to the center after the MMT course, during the last 6 months for treatment of addiction, literacy, hearing and speech impairment, access On the phone, no psychosis, no other treatments at the same time (other psychotherapies, NA, etc.). Exclusion criteria: Unwillingness to continue participating in the study, absenteeism, any serious health problems that prevent the person from continuing to participate in the study (hospitalization, etc).

Intervention groups

the "lapse management" protocol and the calendar slip self-assessment technique will be divided into 4 90-minute sessions in small groups of 2-3 (one session per week). Will be provided for the experimental group. In addition, the intervention group will receive follow-up and individual telephone counseling once a week for 4 weeks. The control group received no intervention. Only the landslide management package will be provided to the control group at the post-test stage for ethics compliance.

Main outcome variables

craving : relapse risk : abstinence self-efficacy of

substances

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045108N2**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Hoda Khoshbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3223 9917

Email address

hoda-khoshbakht@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the "lapse management" training on craving, relapse risk and abstinence self-efficacy of substances in people undergoing methadone maintenance treatment.

Public title

The effect of the "lapse management" training on craving, relapse risk and abstinence self-efficacy of substances in people undergoing methadone maintenance treatment.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Individual's willingness to participate in the study male age 18-50 years after MMT course have been referred to the center for treatment of addiction for the last 6 months literacy hearing and speech impairment access to Telephone absence of psychosis absence of other therapies at the same time (other psychotherapies, NA, etc.)

Exclusion criteria:

Unwillingness to continue participating in the study absenteeism any serious health problems that prevent the person from continuing to participate in the study (hospitalization, etc.)

AgeFrom **18 years** old to **50 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **76****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization : The method would be to randomly select a colored sphere from two in-box spheres

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the data analyzer is unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

No.48, Moalem5, West Moalem Ave

City

Birjand

Province

South Khorasan

Postal code

9717937715

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.BUMS.REC.1398.266

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

"Lapse Management" training

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes**1****Description**

Craving Score in Tiffany's Drug Abuse Questionnaire

Timepoint

Before and after the intervention and 1 month after the intervention

Method of measurement

Tiffany's Drug Abuse Craving Questionnaire,

2**Description**

Relapse Risk Scale on Ogai-Risk Relapse Risk Scale

Timepoint

Before and after the intervention and 1 month after the intervention

Method of measurement

Ogai-Risk Relapse Risk Scale

3**Description**

abstinence self-efficacy of substances Scale in Martin Goleman abstinence self-efficacy of substances Questionnaire

Timepoint

Before and after the intervention and 1 month after the

intervention

Method of measurement

Martin Goleman abstinence self-efficacy of substances
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The "Lapse Management" protocol and the calendar lapse self-assessment technique will be presented to the experimental group in 4 90-minute sessions in small groups of 2-3 (one session per week). In addition, the intervention group will receive once a week They will undergo follow-up and individual telephone counseling for 4 weeks

Category

Prevention

2

Description

Control group: There is no intervention for control group. Only the lapse management package will be provided to the control group in the post-test for ethics compliance.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Addiction Treatment Center No.1-4

Full name of responsible person

Ali Akbar Esmaeili

Street address

Taleghani 7-Taleghani Ave

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9714811151

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ERHL@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

dr.Tooba Kazemi

Street address

Vice Chancellor for Education and Research, Second Floor, Vice Chancellor for Research and Technology, Ghafari Ave.

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9717853577

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research@bums.ac.ir

Grant name

Birjand University of Medical Sciences

Grant code / Reference number

456019

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Private

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

Birjand University of Medical Sciences

Full name of responsible person

Hoda Khoshbakht

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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)

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