

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of cognitive hypnotherapy (COGNITIVE HYPNOTHERAPY) in preventing the relapse of opium use in men treated with methadone compared to the control group in the addiction treatment center.

Protocol summary

Study aim

Determining the effect of cognitive hypnotherapy in preventing the relapse of opium use in men treated with methadone in the addiction treatment center affiliated to 5 Azar Hospital in 2023

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 38 patients. The rand function of Excel software was used for randomization.

Settings and conduct

place: Addiction center affiliated with 5 Azar Hospital, Gorgan The samples are easily selected from the referring patients and are divided into two intervention groups (methadone and cognitive hypnotherapy) and control group (only methadone). After obtaining ethical permits and obtaining informed consent from the patients, first a checklist of their demographic variables will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria : • All opium consuming men who have completed a one-month detoxification course and are undergoing maintenance treatment with methadone. • Age 18-55 years, • Not using other drugs and narcotic drugs for a month before • At least primary education • No history of using stimulants Exit criteria: Absence of more than 2 sessions of cognitive hypnotherapy. • The patient's non-cooperation to monitor the urine test before intervention, after cognitive hypnotherapy and 3 months and 6 months after treatment sessions. • Serious medical illness or major psychiatric disorder (depression, psychosis, etc.) based on a clinical interview by a psychiatric assistant.

Intervention groups

For the cognitive hypnotherapy intervention group, including 8 sessions of 60 minutes (the number of people in each session is maximum 8 people), it will be held

once a week by a psychiatric specialist and relaxation by a psychiatric assistant. For the control group, only methadone is administered.

Main outcome variables

1- Impulsivity 2- Desire to consume shortened items.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170108031818N4**

Registration date: **2023-05-20, 1402/02/30**

Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**

Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

fatemeh mehravar

Name of organization / entity

Golestan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20
Expected recruitment end date
2023-12-11, 1402/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of cognitive hypnotherapy (COGNITIVE HYPNOTHERAPY) in preventing the relapse of opium use in men treated with methadone compared to the control group in the addiction treatment center.

Public title
The effect of cognitive hypnotherapy in preventing the relapse of opium use in men treated with methadone

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All opium consuming men who have completed a one-month detoxification course and are undergoing maintenance treatment with methadone and have a file in the addiction treatment center affiliated to 5 Azar Hospital in Gorgan. Age 18-55 years Not using other drugs and narcotic drugs for a month before At least elementary education No history of stimulant drug use
Exclusion criteria:
Absence of more than 2 sessions of cognitive hypnotherapy Non-cooperation of the patient to monitor the urine test before intervention, after cognitive hypnotherapy and 3 months and 6 months after treatment sessions. Serious medical illness or major psychiatric disorder (depression, psychosis, etc.) based on a clinical interview by a psychiatric assistant

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are placed in one of the treatment groups including only methadone treatment or in the treatment group with methadone and cognitive hypnotherapy as a simple randomization and by lottery.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, shast kola St.,

City

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Postal code

49157468

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.GOUMS.REC.1401.602

Health conditions studied

1

Description of health condition studied

Men treated with methadone

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Opium relapse

Timepoint

3 months later and 6 months later.

Method of measurement

The morphine urine test is a multi-drug test, and if morphine is positive in this test, it is considered as a relapse of drug abuse.

Secondary outcomes

1

Description

impulsiveness

Timepoint

3 months later and 6 months later.

Method of measurement

Ernst Barratt Impulsivity Questionnaire

2

Description

Reduced drug cravings

Timepoint

3 months later and 6 months later

Method of measurement

with the Abbreviated Substance Craving Scale

Intervention groups

1

Description

Intervention group: For the cognitive hypnotherapy intervention group, including 8 sessions of 60 minutes (the number of people in each session is maximum 8 people), it will be held once a week by a psychiatric specialist, and relaxation will be conducted by a psychiatric assistant. Cognitive hypnotherapy will consist of 8 sessions of 60 minutes that will be held once a week. In the first session, along with getting to know the patient and the current life situation of the patient and his family, as well as explaining the hypnosis treatment program and examining the patients' views on hypnosis, the progressive muscle relaxation method will be taught to the patients. At the end of the session, they are asked to do this exercise for 20 minutes every day until the next week, when it is time for the second session. In the second session, the patient will be explained about the unconscious and the effect of insinuations on it, hypnotherapy, insinuations related to relaxation and reducing mental pressure, and teaching exercises will be done. The purpose of the third session is to increase self-confidence and calmness in the patient. They will be familiar with the reminders of drug addiction such as time, place, friends, music, etc. The fourth session: While deepening the trance, they will learn about the harms of drug use and its negative effects. 5th and 6th session: While taking the patients to the deepest depth of trance, insinuations of aversion to substances will be done. Seventh session: In deep ecstasy, the positive effects of staying in the desert, such as taking care of personal and family matters, deepening family relationships, work progress and prevention of damages, increasing self-confidence and morale of oneself and family members, educational progress of children, etc. will be suggested. The eighth session: The exercises that are done in the previous sessions will be reviewed and conditional suggestions will be made to make it easier to induce trance in the patient at home, and the patient will be told about self-hypnosis to eliminate the problems that arise as a result. Quitting occurs for him to use (such as insomnia, restlessness, pain, depression and temptation). The follow-up of patients after the completion of cognitive hypnotherapy sessions will be 3 months later and 6 months later. In this way, during a phone call with the participants, they are requested to come for a morphine urine test. The positive result indicates the existence of drug use during the last three days and is considered as a relapse of drug abuse.

Category

Prevention

2

Description

Control group: Methadone only

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

De-addiction center affiliated with Panj Azar Hospital, Gorgan

Full name of responsible person

Mohammad Zaman Kamkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan 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

Gorgan 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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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