

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

Iran (Islamic Republic of)

##### Phone

+98 912 893 7199

##### Email address

mehravar10261@goums.ac.ir

##### 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**

Gorgan

**Province**

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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

##### **Street address**

Golestan University of Medical Sciences, Shast kola St.

##### **City**

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##### **Phone**

+98 911 371 5318

##### **Email**

kamkarYR@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Gorgan University of Medical Sciences

##### **Full name of responsible person**

Narges Beigom Mirbehbahani

##### **Street address**

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merbehbahani@yahoo.com

#### **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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Zaman Kamkar

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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kamkarYR@yahoo.com

**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