

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

cognitive - behavior therapy effect on insomnia in patients undergoing methadone maintenance treatment at Shafa hospital , Rasht

Protocol summary

Summary

This study is a double blind randomized clinical trial. The participants are substance dependent patients aged 18-60 years that are managed with methadone maintenance therapy in Shafa Hospital. These patients have insomnia that is confirmed by Pittsburgh Sleep quality index (PSQI) and psychiatric interview (on DSM-IV-TR criteria). After considering inclusion criteria, 30 patients are enrolled. After informing written consent, the patients are allocated randomly to treatment or control groups. At first, a demographic questionnaire is filled and a urinary screening test for substance (opium, methamphetamine, benzodiazepine) is performed. In treatment group, the patients participate in weekly cognitive behavioural therapy sessions for 8 weeks. A clinical psychologist manages this 45 minutes sessions. In control group, the patients participate in weekly placebo behavioural therapy sessions for 8 weeks. A psychiatric resident manages this 45 minutes sessions. The urinary screening test for substance is performed weekly. In the end of 4th and 8th weeks, another psychiatric resident fills PSQI questionnaire.

General information

Acronym

Cognitive behavioral therapy - CBT

IRCT registration information

IRCT registration number: **IRCT201206011483N3**

Registration date: **2012-06-09, 1391/03/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-09, 1391/03/20

Registrant information

Name

Mir Mohammad Jalali

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice-chancellorship for research, Guilan university of medical sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

cognitive - behavior therapy effect on insomnia in patients undergoing methadone maintenance treatment at Shafa hospital , Rasht

Public title

psychotherapy effect on insomnia in patients undergoing methadone maintenance treatment at Shafa hospital , Rasht

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age between 18-60 2- Academic level above high school 3- Pittsburgh Sleep Quality Index

>= 5 and confirmation of this diagnosis in psychiatric interview (on DSM-IV-TR criteria). 4- No comorbid psychiatric disorders (Bipolar I or II disorder, Schizophrenia, Major depression disorder in last month, Anxiety disorder) 5- No related chronic medical disease with insomnia 6- Known stabilization dosage of methadone maintenance therapy 7- No sedative drugs usage in last week Exclusion criteria: 1- No continuous presence in weekly treatment sessions 2- No comorbid substance abuse or usage of sedative drugs in period of methadone maintenance therapy (except nicotine usage) 3- Discontinuation of methadone maintenance therapy 4- Substance withdrawal symptoms

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

vice-chancellorship for research, Guilan university of medical sciences

Street address

Siadeti street, Namjoo street

City

Rasht

Postal code**Approval date**

2012-05-23, 1391/03/03

Ethics committee reference number

1910095607

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

insomnia

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

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

PSQI score

Timepoint

before intervention, the end of fourth and eighth weeks

Method of measurement

PSQI test

Secondary outcomes

empty

Intervention groups**1****Description**

participation in Behavioral Placebo Therapy sessions for 8 weeks

Category

Other

2**Description**

participation in Cognitive Behavioral Therapy sessions for 8 weeks

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa Hospital

Full name of responsible person

Dr Robabeh Soleimani Talemi

Street address

Shafa hospital, Heshmat Square, Rasht

City

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Guilan University of Medical Sciences
Full name of responsible person
Dr Abdorrasool Sobhani
Street address
Namjoo street- Rasht
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty