

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1324 3085

##### Email address

mmjalali@gums.ac.ir

##### 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**

Rasht

**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

**Contact**  
**Name of organization / entity**  
Guilan University of Medical Sciences  
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Dr Robabeh Soleimani Talemi  
**Position**  
Assistant professor of psychiatry  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**  
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## 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*