

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of Sleep Hygiene Education on sleep quality and mental health in patients with substance abuse and comparison with the control group

#### Protocol summary

##### Study aim

By examining the effect of sleep hygiene education on sleep quality and mental health in patients with substance abuse, we can take effective steps to improve sleep and mental health skills in patients with drug abuse, to lessen the incidence of insomnia. And fall ill.

##### Design

Controversial, community-based, and pragmatic clinical trials, with parallel, one-blind, randomized, randomized groups

##### Settings and conduct

Study in outpatient rehabilitation centers for people with substance abuse and drug abuse centers in Isfahan is available in 70 patients. Sleep quality questionnaire (PSQ) and mental health (DASS-21) are completed before intervention, one month after the intervention and three months after the intervention in both groups. The data analyst is unaware of the educational content and grouping. .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Inclination to participate in the study, aged over 18, having reading and writing skills, drug abuse, confirmed by positive urine test, and PSQI score higher than 5 Non-Inclusion criteria: Adolescents are adolescents with acute psychiatric disorders such as psychosis, diphtheria, schizophrenia. Exclusion criteria: Patients in any case do not wish to continue to participate in the study, or there is a crisis or unexpected incident during their research. Failure to participate at least two educational sessions and changes in treatment overkill for any reason during the intervention and questionnaires that at least 20% have not been completed are removed and replaced with other patients.

##### Intervention groups

In the intervention group, 35 people are randomly assigned to four sessions of counseling by a trained psychologist to discuss sleep hygiene and how to improve sleep quality.

#### Main outcome variables

Study of the Effect of Group Healthy Sleep Health Education on Sleep Quality and Mental Health in Patients with Substance Abuse

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171230038142N2**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

##### Registration date

2018-10-17, 1397/07/25

##### Registrant information

##### Name

Khosro Tavakol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 9134

##### Email address

tavakol@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-03-11, 1397/12/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Sleep Hygiene Education on sleep quality and mental health in patients with substance abuse and comparison with the control group

**Public title**

The effect of Sleep Hygiene Education on sleep quality and mental health in patients with substance abuse

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The desire to participate in the research Age more than 18 years Having reading and writing skills Substance abuse confirmed by positive urine test. PSQI score higher than 5

**Exclusion criteria:**

An addict is a teenager. Acute psychiatric disorders such as psychosis, diphtheria, schizophrenia.

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling was done by available method in rehabilitation centers and ambulatory outpatient treatment centers with a selection of 70 people, in which 35 individuals were randomly assigned to a control group using a random number table and 35 subjects in the intervention group they got. Subsequently, 4 training sessions of 60-90 minutes were conducted with scheduled educational content for the intervention group by a trained psychologist.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Data was uncovered by the data analyst with the name of the first group (control) and the second group (intervention). He also did not know the educational content.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jereyb St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2018-08-27, 1397/06/05

**Ethics committee reference number**

IR.MUD.MED.REC.1397.009

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

The effect of Sleep Hygiene Education on sleep quality and mental health in patients with substance abuse

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

A study on the effect of sleep hygiene education on sleep quality and mental health in patients with substance abuse through mental health questionnaire (DASS-21) and sleep quality (PSQ). Both questionnaires have a score of 21-0. The higher the rating represents the higher the quality.

**Timepoint**

Before the intervention begins, one month after the intervention and three months after the last intervention session.

**Method of measurement**

The score obtained from the mental health questionnaire (DASS-21) and sleep quality (PSQ) in the three stages before the one month after the start and three months after the intervention. Each of the two questionnaires has a score of 21-0. The higher the rating represents the higher the quality.

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Received 4 sessions of 60-40 minute group training on the effect of sleep hygiene on the quality of sleep and mental health in patients with drug abuse

#### Category

Rehabilitation

### 2

#### Description

Control group: Did not receive training.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehabilitation centers and outpatient treatment centers in Isfahan

##### Full name of responsible person

Zahra Amini

##### Street address

Isfahan University of Medical Sciences, Hezar Jereyb St.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 0048

##### Email

zahraamini63@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Zahra Amini

##### Street address

Isfahan University of Medical Sciences, Hezar Jereyb St.

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##### Province

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##### Email

zahraamini63@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Zahra Amini

##### Position

Assistant Professor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Public Health/Community Medicine

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Zahra Amini

##### Position

Assistant Professor

**Latest degree**

Medical doctor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The information can be shared with the permission of the research and student vice president of Isfahan University of Medical Sciences after being unidentifiable.

**When the data will become available and for how long**

Two years after the publication of the results and after obtaining permission from the Research and Student Vice-Dean of Isfahan University of Medical Sciences is available.

**To whom data/document is available**

Students and professors of the Department of Medicine, Psychology and Consultation

**Under which criteria data/document could be used**

If the results are compared with the next results or any research that is similar or in line with the continuation of the study.

**From where data/document is obtainable**

After informing the email zahraamini63@gmail.com and with the permission of the research and student vice president of Isfahan University of Medical Sciences

**What processes are involved for a request to access data/document**

Sending a request to e-mail zahraamini63@gmail.com and obtaining permission from the Research and Student Vice-Dean of Isfahan University of Medical Sciences.

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Amini

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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