

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

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Isfahan University of Medical Sciences, Hezar Jereyb St.

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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

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Isfahan University of Medical Sciences, Hezar Jereyb St.

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zahraamini63@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

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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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