

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of sleep hygiene training on sleep quality and blood pressure in patients with blood pressure and sleep disorders

#### Protocol summary

##### Study aim

The relationship between sleep hygiene and blood pressure control

##### Design

Clinical trial with control group, with parallel groups, randomized, phase 2-3 on 86 patients. spss software was used for randomization.

##### Settings and conduct

86 patients were selected in Ibn Sina Health Center of Isfahan. Blood pressure of patients following the principles of standard measurement (not using stimulants and caffeinated compounds half an hour before the measurement, the selected arm is bare and free of scars, lymphedema or arteriovenous fistula, at least 5 minutes before in a sitting position so that the legs and waist fully in contact with the ground and the seat, the brachial artery is parallel to the heart and the length and width of the blood pressure cuff are 80% and 40% of the circumference of the arm, respectively) was measured using a Mark Richter hand sphygmomanometer made in Germany. Demographic characteristics including age, gender, height, weight, education and occupation of each patient were recorded. Blood pressure measurement and completion of the Petersburg questionnaire were done before the intervention, one and three months after intervention in both groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient consent to enter the study Age range from 30 to 70 years Suffering from high blood pressure Exclusion criteria: Having a severe physical or mental illness, addiction, pregnancy

##### Intervention groups

We have two groups of 43 people, educational intervention and control. For the intervention group, 4 training sessions were held based on sleep hygiene education and its relationship with blood pressure control.

##### Main outcome variables

Blood pressure, sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220119053760N3**

Registration date: **2023-12-04, 1402/09/13**

Registration timing: **retrospective**

Last update: **2023-12-04, 1402/09/13**

Update count: **0**

##### Registration date

2023-12-04, 1402/09/13

##### Registrant information

##### Name

Neda Abrishami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3778 8089

##### Email address

n.abrshami@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-18, 1399/01/30

##### Expected recruitment end date

2020-08-20, 1399/05/30

##### Actual recruitment start date

2020-08-20, 1399/05/30

##### Actual recruitment end date

2020-08-20, 1399/05/30

##### Trial completion date

2020-08-20, 1399/05/30

### Scientific title

The effect of sleep hygiene training on sleep quality and blood pressure in patients with blood pressure and sleep disorders

### Public title

The relationship between sleep hygiene and blood pressure control

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patient consent to enter the study Age range from 30 to 70 years Patients who, according to the latest guidelines of the Ministry of Health and Medicine, have been diagnosed with high blood pressure or had uncontrolled blood pressure (blood pressure  $\leq$  90.140 mmHg) despite taking medication.

#### Exclusion criteria:

Severe physical or mental illness addiction pregnancy

### Age

From **30 years** old to **70 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **86**

Actual sample size reached: **86**

### Randomization (investigator's opinion)

Randomized

### Randomization description

First, among the clients of Ibn Sina Center in Isfahan city, 86 clients who had high blood pressure ( $\geq$ 140/90) and had a medical record in the center were selected and included in the study. Patients eligible to enter the study received a code in order of entry (from number 1 to number 86), then using these codes and using SPSS software, they were assigned to two groups of 43 people, intervention and control (spss/data/ selected cases).

Allocation of patients into two intervention and control groups was done in a simple random manner. The study was not blinded. The randomization unit is individual.

### 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 Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences , Hezar Jerib St.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Approval date

2019-07-23, 1398/05/01

#### Ethics committee reference number

IR.MUI.MED.REC.1398.005

## Health conditions studied

### 1

#### Description of health condition studied

blood pressure

#### ICD-10 code

R03

#### ICD-10 code description

Abnormal blood-pressure reading, without diagnosis

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

before, one month and three months after the end of the intervention

#### Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

### 2

#### Description

blood pressure

#### Timepoint

before, one month and three months after the end of the intervention

#### Method of measurement

With the help of a mercury pressure gauge

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

43 patients with high blood pressure were trained as follows during four training sessions of 60-75 minutes: Session 1: Defining sleep and explaining the mechanism of sleep and wakefulness, presenting materials related to relaxation techniques to enter a peaceful and pleasant sleep in accordance with the principles of sleep hygiene. Session 2: Explaining the relationship between sleep and blood pressure, examining physiological changes in sleep and sleep disorders in simple language, explaining and interpreting 10 principles of sleep hygiene. Session 3: Investigating the effect of age on sleep, introducing the components of sleep and a brief explanation regarding factors that disrupt sleep (such as sound, light, etc.) and improve it (earmuffs, blindfolds, dark and silent places, etc.) , explanation and interpretation of 13 items from the principles of sleep hygiene. Session 4: Summarizing and reviewing the trainings of the previous sessions and the necessity of adhering to the application of the taught items and timely referrals at one-month and three-month intervals to measure blood pressure and complete the Petersburg Sleep Quality Questionnaire. The educational method included lectures, questions and answers, and discussions in small groups. The sleep quality assessment method was through the Pittsburgh Sleep Quality Index, which was completed before, one month, and three months after the completion of the training. The Petersburg Sleep Quality Questionnaire is a report that examines sleep quality over the past month. This questionnaire has 19 questions with 4 options and contains 9 sections to examine the dimensions of mental quality of sleep, delay in falling asleep, sleep duration, sleep efficiency, sleep disorders, use of sleeping pills, daily dysfunction.

### Category

Lifestyle

## 2

### Description

Control group: They did not receive any training intervention. Their blood pressure was measured before, one month and three months after completing the training. The Pittsburgh Sleep Quality Questionnaire was also completed before, one month and three months after the completion of the training.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ibn Sina Health Center, Isfahan

##### Full name of responsible person

Parastoo Golshiri

##### Street address

Ibn Sina St

##### City

Isfahan

##### Province

Isfahan

##### Postal code

73461-81746

##### Phone

+98 31 3668 0048

##### Email

golshiri@hlth.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Gholamreza Asgari

##### Street address

Vice Chancellor for Research and Technology,  
Building No. 4, Isfahan University of Medical Sciences  
and Health Services, Hezar Jerib St.

##### City

Isfahan

##### Province

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##### Postal code

81746-73461

##### Phone

+98 31 3668 7898

##### Email

research@mui.ac.ir

#### 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

90

#### 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

Neda Abrishami

##### Position

Student

**Latest degree**

Master

**Other areas of specialty/work**

Biostatistics

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Neda Abrighami

**Position**

Student

**Latest degree**

Master

**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**

All data can be shared after de-identification, 6 months  
after publication of the article.

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

Information can be shared 6 months after the publication  
of the article.

**To whom data/document is available**

physicians

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

The information of this study can be used by doctors,  
internal specialists, endocrinologists, psychologists and  
researchers in the field of non-pharmacological  
interventions. In this regard, if researchers consider  
comparing another educational or therapeutic method  
with the present method, or if they examine the sample  
of patients other than those with blood pressure but with  
sleep disorders, they can benefit from the results of our  
study.

**From where data/document is obtainable**

Send email to: golshiri@hlth.mui.ac.ir Belongs to Dr.  
Prasto Golshiri, Faculty of Medicine, Isfahan University of  
Medical Sciences.

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

Send email to: golshiri@hlth.mui.ac.ir

**Comments**