

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)

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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

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Ibn Sina St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

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Vice Chancellor for Research and Technology,
Building No. 4, Isfahan University of Medical Sciences
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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 scientific inquiries**Contact****Name of organization / entity**

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Position

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

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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