

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of adjustment of environmental factors on sleep quality of patients admitted to the cardiology unit of Shahid Modarres Hospital of Saveh

Protocol summary

Study aim

Determining the effect of adjustment of environmental factors on sleep quality in patients hospitalized in Coronary Care Unit

Design

Randomized clinical trial with control group, parallel groups, one-blinded.

Settings and conduct

The present study will be conducted at Modarres Hospital on patients hospitalized in Coronary Care Unit. The analyzer will not know how to place the samples in the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The willingness to participate in the study Passes at least 6 days after hospitalization Don't use of somnifacient drugs 18 to 65 years old Exclusion criteria: Unwilling to participate in the study History of sleep disorder

Intervention groups

For intervention group, measures are taken to moderate environmental factors, including downsizing of telephone calls, alarms of devices, shutdown of all additional lights during the night, and use of low light during the daytime. Control group samples are in normal condition and receive standard care.

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031328N8**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**

Update count: **0**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

Mahbobeh Sajadi

Name of organization / entity

Arak University of Medical Sciences

Country

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Phone

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Recruitment status

recruiting

Funding source

Expected recruitment start date

1639-01-14, 1017/10/24

Expected recruitment end date

2639-05-24, 2018/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adjustment of environmental factors on sleep quality of patients admitted to the cardiology unit of Shahid Modarres Hospital of Saveh

Public title

Adjustment of environmental factors on the quality of sleep in patients admitted to the Cardiac Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The willingness to collaborate in the study Admission for at least 6 days Do not use hypnotic drugs Having a range of 17 to 64 years old Not having a specific disease, such as hepatitis

Exclusion criteria:

Surrender patient sleep disorder Transferring the patient to other parts

Age

From **17 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

groups over successive but equal intervals.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer will not know how to place the samples in the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Samples were randomly assigned to two intervention and control groups using randomized block assignment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده علوم پزشکی ساوه

Street address

Saveh University of Medical Sciences, Madar Sq.,
Shariati St.

City

Saveh

Province

Markazi

Postal code

3919676651

Approval date

2638-10-17, 2017/07/25

Ethics committee reference number

IR.SVEHUMS.REC1396.13

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality

Timepoint

Before the study and six days after the first day of hospitalization

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: from the third day after the hospitalization, adjustments to the environmental factors (including reduction of light and surplus voices) are performed consecutively for three days.

Category

Lifestyle

2

Description

Control group: from the third day after hospitalization without any changes in the physical conditions of the unit and without any additional work until the 6 days will be monitored.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modares Hospital

Full name of responsible person

Elham Farhadi

Street address

Shahid Modares Hospital, Modarres Sq.

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3915953983
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Saveh 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

Saveh 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
Saveh University of Medical Sciences
Full name of responsible person
Neda Fayazi
Position
Master of Nursing
Latest degree
Master

Other areas of specialty/work

Nursery

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.

When the data will become available and for how long

The beginning of the access period is 12 months after the results are published.

To whom data/document is available

For all researchers

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable

nedafayazi10@yahoo.com Neda Fayazi

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

After receiving the email from the requester, the information will be sent within 2 to 3 business days.

Comments