

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Effect of Sleep Hygiene Education on Sleep Quality of Patients with Heart Failure Hospitalized in Cardiac Care Units

#### Protocol summary

##### Study aim

Effect of Sleep Hygiene Education on Sleep Quality of Patients with Heart Failure Hospitalized in Cardiac Care Units of Urmia Teaching Hospitals 2017-2018

##### Design

In this study, the units were selected by available method and then allocated randomly to two groups of intervention and control. The sample size in total was 70 persons in two groups of 35. The tools used in this study were the form of population profile Cognitive, weekly recording and the Pittsburgh Sleep Quality Index

##### Settings and conduct

Patients at the discharge stage from Seyyedol Shohada Medical Center of Urmia

##### Participants/Inclusion and exclusion criteria

In this study, patients with heart failure grade 2 and 3 in the age range of 30-70 years of age who have self-care ability and are available within three months are included in the study, and in the event of a patient's death or unwillingness to continue studying

##### Intervention groups

After one month of discharge, samples are taught through a booklet in the form of a sleeping public health. A pre-test test is performed and a weekly recording record sheet is provided to the samples. After one month, the post-test is done

##### Main outcome variables

Helping improve sleep quality in patients with heart failure and reducing insomnia from insomnia during the day

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180811040760N1**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

##### Registration date

2018-09-03, 1397/06/12

##### Registrant information

###### Name

Vahideh sadat Majidi khanyani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7787 6526

###### Email address

parastari\_bep@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-05, 1396/11/16

##### Expected recruitment end date

2018-03-30, 1397/01/10

##### Actual recruitment start date

2018-02-05, 1396/11/16

##### Actual recruitment end date

2018-04-19, 1397/01/30

##### Trial completion date

empty

##### Scientific title

Effect of Sleep Hygiene Education on Sleep Quality of Patients with Heart Failure Hospitalized in Cardiac Care Units

##### Public title

"Effect of Sleep Hygiene Education on Sleep Quality of Patients with Heart Failure"

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with Heart Failure Heart Failure class II, III  
 Having full vigilance The ability to communicate effectively  
 Self-care ability Availability and control within 3 months  
 Having no illnesses that disrupts the results of the study

**Exclusion criteria:**

Patient death Unwillingness to continue reading by the patient  
 Not attending training sessions for more than one meeting  
 Failure to complete the weekly registration record for more than two days

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

Actual sample size reached: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, units were selected by available method and divided into two groups of intervention and control by selecting two red and blue cards

**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 Urmia University of Medical Sciences

**Street address**

Medical faculty of Orumi Medical University, Resalat Ave

**City**

Orumieh

**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2018-01-03, 1396/10/13

**Ethics committee reference number**

IR.UMSU.REC.1396.348

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

Sleep Hygiene Education

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

Sleep Quality

**Timepoint**

One month after the discharge, samples are trained from the hospital and one month after the intervention, the result of the training is measured

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: After obtaining permission from the research council of the university and receiving the ethics code from the Ethics Committee, the researcher referred to the research environment and, after coordinating with the management of the specialized and specialized cardiology center of Seyyed Alshohada, patients with heart failure had entry conditions in the hospital Hospitalized and in the clearance stage; available in an accessible way, after giving explanations about the title of the research plan and its goals, will provide the company's consent form to the research and the demographic questionnaire to those who wish to participate in the project. After reaching the required amount of research samples, the researcher will arrange a meeting in person with all the individuals and after providing explanations on how to complete the weekly registration record, it will be provided to patients and will ask them to submit this sheet Complete for 4 weeks on a daily basis. After completing the weekly sleep schedule, the Pittsburgh Sleep Quality Index was completed by each patient to evaluate the sleep quality of the patients and the samples were randomly divided into intervention and control groups. The researcher in the intervention group, after one month of discharge from the hospital for 5 sessions of an hour, began to teach sleep hygiene based on the latest American National Sleep Association guidelines and authoritative sources in person, using educational slides and training manuals solo will be patient at home

**Category**

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Seyyed Shahada Hospital

**Full name of responsible person**

Vahideh Sadat Majidi Khanyani

**Street address**

Seyyed Shahada Hospital

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Rahim Baghaei

**Street address**

nursing school, Urmia University of Medical Sciences.,  
Nazlou

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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**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Vahideh Sadat Majidi Khanyani

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Rahim Baghaei

**Position**

Associate professor

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Ph.D.

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## Person responsible for updating data

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**Other areas of specialty/work**

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**Province**

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**Phone**

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**Email**

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**Web page address**

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable