

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia 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

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

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Ph.D.

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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