

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

Protocol summary

Summary

The current study examines the effects of multifactorial intervention to improve sleep in patients admitted to coronary care unit. This quasi-experimental study was conducted in 1390 in a hospital doctor Shariati in Iran. The study sample consisted of 60 patients were admitted to the coronary care unit that the following criteria were: Being hospitalized for at least three nights, be aware of time and place and no need for cardiopulmonary resuscitation, no medical history of neurological and psychiatric disorders, not receiving medications affecting sleep, like amphetamines, opiates at night, and if the patient is discharged in less than three days, need for CPR during the study and receiving disturbing sleep medications such as drugs, diuretics, amphetamines, opiates at night, samples were excluded. Specimens available for study were selected and control group was tested in the first and then experimental group. Nursing Based Multifactorial intervention was doing in the first three night's admission in experimental group and includes: reducing the environmental factors disturb sleep, changing care practices for sleep was not interrupted and in the control group took part in the routine caring. Sleep quality was measured by Pittsburgh questionnaire. With the analyzing of data in both groups, significant improvement in the experimental group is expected to sleep.

General information

Acronym

The effect of Nursing interventions on sleep of hospitalized patients

IRCT registration information

IRCT registration number: **IRCT201109171599N12**
Registration date: **2011-12-11, 1390/09/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-11, 1390/09/20

Registrant information

Name

Mitra Zolfaghari

Name of organization / entity

Tehran University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Medical, Nursing and Health Care Research Center

Expected recruitment start date

2011-09-11, 1390/06/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

Public title

The effect of Nursing based Multifactorial intervention on sleep of hospitalized patients in Coronary care unit

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria of the study; Patients are admitted to the coronary care unit for at least three days; be aware of time and place; and no need for cardiopulmonary resuscitation; no medical history of neurological and psychiatric disorders; not receiving medications affecting sleep, like amphetamines, opiates and sedatives at night. Exclusion criteria of the study: Patients being discharged in less than three days; to receive sedating medications and general anesthesia; need for CPR during the study; neurological and psychiatric diseases in the patient's medical history; receiving medications affecting sleep medications such as diuretics, hypnotics, and amphetamines, opiates at night; and the patient did not wish to continue study.

Age

From 20 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

To reduce the effects of confounding variables, research is conducted in a single CCU Dr.Shariati hospital

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

CENTER OF NURSING AND MIDWIFERY
RESEARCH, Tehran University of Medical Sciences

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TEHRAN UNIVERSITY OF MEDICAL SCEINCES FACUITY
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Postal code

ندارد

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

1468/130/90/3

Health conditions studied

1

Description of health condition studied

Sleep

ICD-10 code

G47.8

ICD-10 code description

Other sleep disorders

Primary outcomes

1

Description

Sleep quality

Timepoint

On the first day and three days after admission

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

1

Description

Sleep quantity

Timepoint

every day for three days

Method of measurement

Researcher made questionnaire

Intervention groups

1

Description

Data quality and quantity of sleep during hospitalization was measured using a questionnaire in experimental group then the intervention is conducted, including: A) Adjusting environmental factors which include: reducing the light and sound and Setting the temperature at night, B) educating nurses about the importance of sleep and sleep in patients with heart disease and insomnia factors, C) changing routine care procedures for patients to improve sleep. Then, the patient's sleep quality is measured again by using the same questionnaire three days after admission.

Category

Behavior

2

Description

Data quality and quantity of sleep during hospitalization was measured using Pittsburgh questionnaire in control

group and then qualitative and quantitative characteristics of the patients with the sleep questionnaire is measured again three days after admission while routine care during in these three days for the control group was done.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Doctor Shariati Hospital

Full name of responsible person

Pouya farokh nezhad afshar

Street address

Tehran- kargar street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mitra Zolfaghari

Street address

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences, FACULTY OF NURSING AND MIDWIFERY, EAST NOSRAT ST, SQUARE OF THOHID, THERAN, IRAN

City

Tehran

Grant name

Phd

Grant code / Reference number

در حال بررسی

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nursing and Midwifery Care Research Center, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Mitra Zolfaghari

Position

Instructor

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty