

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of applying continuous care model on sleep quality in patients with stable heart failure

Protocol summary

Summary

Current study Experimental (RCT) is to determine the effect of applying continuous care model on sleep quality in patients with chronic heart failure. Patients are placed in two experimental and control groups. Inclusion criteria included the following people older than 18 years old, patients with stable chronic heart failure, ejection fraction less than 45%, patients with NYHA class II-IV. Exclusion criteria: unwillingness to continue participation in the study, crisis or an unforeseen accident the patient had a history of psychiatric disorders, pregnant women patients with renal failure requires dialysis. Research tools: Pittsburgh Sleep Quality Scale, and a questionnaire of personal information. Intervention: Implementation of continuous care model in the experimental group for three months is based on continuous care model. Continuous care model consists of four stages: orientation, sensitization, control and evaluation components. Data analysis using descriptive and inferential statistics (chi-square tests, t-test, regression, covariance analysis) will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010425843N1**

Registration date: **2016-04-03, 1395/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Hajar Sadeghi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of applying continuous care model on sleep quality in patients with stable heart failure

Public title

The effect of applying continuous care model on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: people older than 18 years old, patients with stable chronic heart failure, ejection fraction less than 45%, patients with NYHA class II-IV. Exclusion criteria: unwillingness to continue participation in the study, crisis or an unforeseen accident the patient had a history of psychiatric disorders, pregnant women patients with renal failure require dialysis.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Sardasht

City

Arak

Postal code**Approval date**

2015-03-16, 1393/12/25

Ethics committee reference number

14-176-93

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

Heart disease

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes**1****Description**

Quality of sleep

Timepoint

Before and after intervention

Method of measurement

Pittsburgh Sleep Quality Index(PSQI)

Secondary outcomes

empty

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

Intervention group: The Pittsburgh Sleep Quality Index by the control group and the test is completed, follow-up care model consists of four phases: orientation, sensitization, control and evaluation of Pittsburgh measured in the test group .

Category

Behavior

2**Description**

Control group: Control group received usual care.

Category

N/A

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

Amirkabir hospital

Full name of responsible person

Hajar Sadeghi

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Arak, Nurse Sq, Alamolhoda St, Amir kabir Hospital

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2**Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

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

Vice chancellor for research of Arak University of

Medical Sciences
Full name of responsible person
Akram Moslemi
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Arak University of Medical Sciences, Alamolhoda St.,
Rahahan Sq.
City
Arak
Grant name
-
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Arak 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

Name of organization / entity
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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