Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

+98 86 3417 3503

Email address

haj.sadeghi@arakmu.ac.ir

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
Street address
Arak, Nurse Sq, Alamolhoda St, Amir kabir Hospital
City
Arak

2

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Hajar Sadeghi
Street address
Arak, Sardasht, Amiralmomenin hospital
City
Arak

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

Street address

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

Arak University of Medical Sciences

Full name of responsible person

Hajar Sadeghi

Position

MSc, Faculty member

Other areas of specialty/work

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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