Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of progressive muscle relaxation on sleep quality in patients with chronic heart failure

Protocol summary

Summary

Objectives: the aim of this study is to determine the effect of progressive muscle relaxation on sleep quality in patients with chronic heart failure. Design: this non-blinding randomized controlled trial is done in CCU wards of Fatemeh Zahra Hospital in Sari. Study population: patients with chronic heart failure. Inclusion criteria: age older than 18 yearsold; NYHA class 2 and 3; at least 3 months past history; Pittsburgh score of 5 or higher; no consumption of sedatives, antidepressants and antihistamines. Exclusion criteria: no cooperation; consumption of sedatives; not doing relaxation more than 10% (6 times) during the study; be candidate for cardiac invasive procedures. Sample size: 90 patients are divided into two groups: intervention and control. Intervention: progressive muscle relaxation is taught during three sessions in each patient. The first session is hold after stabilization of clinical signs, for 30 minutes. The second session is done at the evening of the same day, for 15 minutes. The third session is hold the next morning, for 15 minutes. After obtaining properly feedback, relaxation educational booklet associated with a CD and an event recording check list are delivered to patients and asked them to do this technique twice daily (once in the morning and once at night before sleeping), for one month . In order to evaluation,telephone follow up of patients is done by researcher weekly. The patients of control group will receive the usual care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428101N2**
Registration date: **2016-07-24, 1395/05/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-24, 1395/05/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progressive muscle relaxation on sleep quality in patients with chronic heart failure

Public title

Sleep quality in heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age older than18 years old; NYHA class 2 and 3; at least 3 months past history; established clinical signs; Pittsburgh score of 5 or higher; no consumption of sedatives, antidepressants and antihistamines. Exclusion criteria: no cooperation, consumption of sedatives, not doing relaxation more than 10% (6 times) during the study and be candidate for cardiac invasive procedures.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

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 Mazandaran University of Medical Sciences

Street address
Nursing and Midwifery Faculty, Vesal street, Sari

City
Sari

Postal code
4816715793

Approval date
2016-06-28, 1395/04/08

Ethics committee reference number
IR.MAZUMS.REC.95.2193

Health conditions studied

1

Description of health condition studied
Sleep Quality

ICD-10 code
G47

ICD-10 code description
Sleep Disorders

Primary outcomes

1

Description
Sleep quality

Timepoint
Before Intervention, one month after Intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group, progressive muscle relaxation is taught during three sessions in each patient.The first session is hold after stabilization of clinical signs, for 30 minute. The second session is done at the evening of the same day, for 15 minutes. The third session is hold the next morning, for 15 minutes. After obtaining properly feedback, relaxation educational booklets associated with a CD and an event recording check list are delivered to the patients and asked them to do this technique twice daily(once in the morning and once at night before sleeping) for one month. In order to evaluation,telephone follow up of patients is done by researcher weekly.

Category
Behavior

2

Description
The patients of control group will receive the usual care.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Zahra Hospital, Sari

Full name of responsible person
Samaneh Yousefi

Street address
Fatemeh Zahra Hospital, Military Boulevard, Municipality Square, Sari

City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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Nursing and Midwifery Faculty, Vesal street, Sari
City
Sari
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, Mazandaran 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

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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