

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Zohreh Taraghi

Name of organization / entity

Mazandaran University of Medical Sciences

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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 than 18 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 held 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 held 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 evaluate, 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

Street address

Nursing and Midwifery Faculty, Vesal street, Sari

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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

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Samaneh yousefi

Position

Master Student in Critical care nursing

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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