

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of Benson Relaxation Technique on quality of sleep in patients with Chronic Heart Disease.

Protocol summary

Summary

This randomized controlled clinical trial to evaluate the effect of Benson Relaxation Technique on quality of sleep in 60 patients with Chronic Heart Disease in Vasei hospitals in Sabzevar. Inclusion criteria: Confirmed diagnosis of Heart Failure or Myocardial Infarction; Age 30 to 60 years; Not having psychiatric disorder; Not having chronic disease; Not using sedatives drug. Exclusion criteria: Reluctance to continue participating in the exercises; Presence of crisis or disaster during the intervention period; Death; Use of sedatives drug. After obtaining permission from the Research Ethics Committee of Sabzevar University of Medical Sciences and informed consent of patients entering the study, patients were randomly allocated to two groups, 30 patients in experimental group and 30 in control group. The experimental group receive supportive intervention and get education of Benson Relaxation Technique and every patient get one CD and pamphlet for use in home. Patients in experimental group did Benson Relaxation Technique for 20 minute, twice a day during one month. The control group did not receive any intervention. The Pittsburgh Sleep Quality Index completed before and one month after intervention for all patients in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052617865N1**
Registration date: **2014-06-18, 1393/03/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-18, 1393/03/28

Registrant information

Name

Seyed Morteza Hashemi Nik

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 57 1444 6070

Email address

morteza.hasheminik@yahoo.com

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2014-01-05, 1392/10/15

Expected recruitment end date

2014-03-18, 1392/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Benson Relaxation Technique on quality of sleep in patients with Chronic Heart Disease.

Public title

Effect of Benson Relaxation on quality of sleep in cardiac patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Confirmed diagnosis of Heart Failure or Myocardial Infarction; Age 30 to 60 years; Not any psychiatric disorder; Not any chronic disease; Not using sedatives drug. Exclusion criteria: Reluctance to continue

participating in the exercises; Presence of crisis or disaster during the intervention period; Death, Use of sedatives drug.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Sabzevar University of Medical Sciences

Street address

School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar

City

Sabzevar

Postal code

Approval date

2013-12-26, 1392/10/05

Ethics committee reference number

medsab.rec.92.10

Health conditions studied

1

Description of health condition studied

Chronic Heart Disease

ICD-10 code

I25.9 / I5

ICD-10 code description

Chronic Ischaemic Heart Disease, unspecified / Heart Failure, unspecified

Primary outcomes

1

Description

Quality of sleep in patients with Chronic Heart Disease

Timepoint

Before the intervention and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: After obtaining permission from the Research Ethics Committee of Sabzevar University of Medical Sciences and informed consent of patients entering the study, patients were randomly allocated to two groups, 30 patients in experimental group and 30 patients in control group. The experimental group receive supportive intervention and get education of Benson Relaxation and every patient get one CD and pamphlet for use in home. Patients in experimental group did Benson Relaxation for 20 minute, twice a day during one month. The Pittsburgh Sleep Quality Index completed before and one month after intervention for patients in experimental group.

Category

Behavior

2

Description

Control group: After obtaining permission from the Research Ethics Committee of Sabzevar University of Medical Sciences and informed consent of patients entering the study, patients were randomly allocated to two groups, 30 patients in experimental group and 30 patients in control group. The control group did not receive any intervention. The Pittsburgh Sleep Quality Index completed before and one month after Research for patients in control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of education, research and treatment of Vasei Sabzevar

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Moosa Reza Tadayonfar

Street address

School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Seyed Morteza Hashemi Nik

Position

Master Student Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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Position

MSc / Member of Faculty

Other areas of specialty/work

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Person responsible for updating data

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Position

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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