

# 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**

**Street address**

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criticalcare2013@yahoo.com

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## Person responsible for scientific inquiries

### Contact

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Roya Akbarzadeh

**Position**

MSc / Member of Faculty

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Web page address**

## 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*