Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Survey and comparing the effects of Benson relaxation and Progressive muscle relaxation on quality of sleep in patients after coronary artery bypass surgery

Protocol summary

Summary

The objective of this clinical trial is to survey and compare the effects of benson relaxation and progressive muscle relaxation on quality of sleep in patients after coronary artery bypass surgery. The study population will be patients undergoing coronary artery bypass surgery in the shaid beheshtiy and valyasr hospital. One hundred twenty praticipants assigned to of Benson relaxation and progressive muscle relaxation or control groups. Methods: after surgery, when patients were transferred to the part, in the Second day, researcher will teach relaxation to patients by Mp3player. Then, a Mp3player and record sheet will be give to research unit. Patients will done the exercises twice a day fot 4 week at 20 minute using arelaxation Mp3player at home and after each time, the data will be record in the daily recorde sheet at the end of one and three week, researcher will discuss with phone calls about the research units relaxation exercise and problems. Before and four week after intervention, pisttburgh sleep quality index will be compelet. The control group will not receive any type of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703123064N6**
Registration date: **2017-04-19, 1396/01/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research (Research and Technology), Shahroud University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey and comparing the effects of Benson relaxation and Progressive muscle relaxation on quality of sleep in patients after coronary artery bypass surgery

Public title

Survey and comparison the effect of relaxation on sleep quality of patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 40 to 75 years old; having written

knowingly informed consent; No previous history of heart surgery; No history of mental illness diagnosed doctor; Bypass surgery Coronary artery bypass due to stenosis 2 vessels to 4 vessels; Poor sleep quality based on answers to a questionnaire Pittsburgh Sleep Quality (In Pittsburgh Sleep Quality Index (PSQI) earn score of 5-21); Do not use Sedations drugs other than routine. Exclusion criteria during study: Using any of the relaxation methods expect Benson and progressive during the study period; Not wanting to continue to contribute in study; do not receive sedative by routine in the part.

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

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 Shahroud University of Medical Sciences

Street address
Hafte-Tir square, Shahroud University of Medical Sciences

City
Shahroud

Postal code
3614773955

Approval date
2017-03-07, 1395/12/17

Ethics committee reference number
IR.SHMU.REC.1395.181

Health conditions studied

1

Description of health condition studied
Sleep disorder

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
Sleep quality

Timepoint
pre- intervention and 4 weeks after intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
In the Benson relaxation group, one sessions of relaxation training will hold during 20-30 minutes by MP3 player through headphone. Then a MP3player and relaxation record sheet will give to the subjects and they will be ask to do relaxation practices twice a day in 20 minutes for 4 weeks. at the end of one and three week, researcher will call and speak about the practice and the their potential problems. 4 weeks after the start of study the Pittsburgh Sleep Quality Index will be completed.

Category
Behavior

2

Description
In the progressive muscle relaxation group, one sessions of relaxation training will hold during 20-30 minutes by MP3 player through headphone. Then a MP3player and relaxation record sheet will give to the subjects and they will be ask to do relaxation practices twice a day in 20 minutes for 4 weeks. at the end of one and three week, researcher will call and speak about the practice and the their potential problems. 4 weeks after the start of study the Pittsburgh Sleep Quality Index will be completed.

Category
Behavior

3

Description
In the control group, at the end of one and three week telephone contact is established in order to maintain contact. After 4 weeks, the Pittsburgh Sleep Quality Index will be completed again.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Valyasar hospital
Full name of responsible person
Dr Hossein Bagheri
Street address
Amin Boulevar, gomhori Boulevard,Valyasar hospital
City
Qom

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Hossein Bagheri
Street address
Shahid beheshti Boulevar, Imam street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad -Hassan Emamian
Street address
Hafte-Tir Square, Shahroud University of Medical Sciences
City
Shahroud
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 Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hossein Bagheri
Position
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Person responsible for scientific 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