Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of combination effect of Benson’s relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

Protocol summary

Study aim
Comparison of combination effect of Benson’s relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

Design
Four groups clinical trials, With a control group, Randomized by senary random block with no permutations with 64 patient

Settings and conduct
64 Patients referring to the cardiac care units of the Shahid Rajaee hospital of Gachsaran, through continuous sampling will enter to study. The Benson relaxation method will be performed by the patient on the day after the training.Instructions for doing these steps will be provided through the audio file by the researcher. The warm Foot baths will perform up to 10 cm above the ankle with 40 ° C water for 30 minutes, 1hour before bedtime. The patients in the combined group are asked to first bath their feet in water for 30 minutes and then Perform relaxation for 20 minutes in accordance with the above mentioned protocols.In the control group, nothing will be done in 3 consecutive nights of intervention,Interventions will take place for three consecutive days.All groups will receive regular care of the unit. The SMHSQ and Beck's questionnaire will be completed for three days.

Participants/Inclusion and exclusion criteria
Inclusion criteria:1-Diagnosis of acute coronary syndrome that 24-48 hours passed from the time they began to be hospitalized 2-ack of acute or chronic psychiatric or anxiety disorders 3-At least reading and writing skills4-Age 65-32 years old5-Complete alert6-A score of 25-16 (moderate anxiety) was obtained based on Beck's questionnaire Exclusion criteria:1-Failure to motivate the patient to continue cooperation 2-Exacerbation of the disease for a period of intervention 3-Death of the patient

Intervention groups
Four groups of Benson's muscle relaxation,Foot bath,Combination group and control

Main outcome variables
Quality of Sleep- Anxiety

General information

Reason for update

Acronym
ACS

IRCT registration information
IRCT registration number: **IRCT20190126042497N1**
Registration date: **2019-02-05, 1397/11/16**
Registration timing: **prospective**

Last update: **2019-02-05, 1397/11/16**
Update count: **0**

Registration date
2019-02-05, 1397/11/16

Registrant information

Name
Hoda Arianpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3620 1449

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hoda.aryanpour@yums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-07, 1397/11/18

Expected recruitment end date

2019-04-07, 1398/01/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination effect of Benson’s relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

Public title

combination effect of Benson’s relaxation technique and Foot bath on Quality of Sleep and Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Acute Coronary Syndrome lack of anxiety or chronic psychatric disorder First time admission in CCU ward Passed at least one night from the patient's hospitalization having written knowingly informed consent Interest in program participation lack of acute or chronic illness At least reading and writing skills Age 65-32 years old Having healthy health (hearing and legs) Complete alert lack of membership in medical treatment services A score of 25-16 (moderate anxiety) was obtained based on Beck's questionnaire Sleeping and relaxing medications are the same Lack of mental and motor disorders Not having eczema or any type of ulcer in your legs Not having diabetic ulcer or diabetic neuropathy diagnosis lack of corporate programs of relaxation; Foot bath and similar techniques

Exclusion criteria:

Failure to motivate the patient to continue cooperation Exacerbation of the disease for a period of intervention Death of the patient

Age

From **32 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with acute coronary syndrome are selected by non probabilistic sampling, but randomly assigned to four intervention groups. In this method, all four states of the group are written on 16 cards and each will be placed in a sealed envelope. These packs are placed in a box, and the researcher does not know which groups of items are to be examined before choosing any of the envelopes. Prior to exposing the units, the researcher assisted in removing one of the envelopes from the box, in which of the 4 illnesses that entered the study would be included.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasouj University of Medical Sciences

Street address

Dr. Shahid Motahari Blvd., Yasouj University of Medical Sciences

City

Yasouj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

75917-41417

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.YUMS.REC.1397.133

Health conditions studied

1

Description of health condition studied

Sleep

ICD-10 code

F51.2

ICD-10 code description

Nonorganic disorder of the sleep-wake schedule

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Quality of Sleep

Timepoint
Measurement of Sleep Quality before the onset of intervention and on the morning of the third, fourth and fifth day of admission after the start of Benson's relaxation & Foot bath
Method of measurement
St Mary’s Hospital Sleep Questionnaire (SMHSQ)

2

Description
anxiety
Timepoint
Measurement of Anxiety before the onset of intervention and on the morning of the third, fourth and fifth day of admission after the start of Benson's relaxation & Foot bath
Method of measurement
Beck Anxiety Inventory (BAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Benson relaxation technique: The Benson's muscle relaxation is performed by the patient in six steps. 1- Stay in a comfortable position 2. Close eyes. 3. Expansion the muscles of the body from the tip to the head 4. Performing the inhale through the nose and exhaling through the mouth and whisper the word desired when exhaling. 5- Perform the above steps for 20 minutes, then open the eyes and do not move for a few minutes. 6. Lack of worry and ignoring disturbing thoughts during relaxation. During the intervention, remove the disturbing thoughts from your mind as much as possible and choose a word that has always reminded him of calm, such as (God, love, sea). Instructions for doing these steps will be provided through the MP3 player and headphones. In this audio file, the instructions are set for 20 minutes and there is no need to set the clock to determine the method duration. In this file, 30 seconds before the completion of the technique, a gentle song will be put to inform the patient about the end of the procedure. To perform muscle relaxation by pulling the curtains at the patient's bed, the patient's privacy is observed and the privacy of the person and providing a quiet and silent environment for sitting with the department's officials is coordinated so that nobody gets into the patient's unit. One day after training the procedures In addition to the usual care of the department, Benson's relaxation procedure is performed every night befor bedtime for three consecutive days by patients and supervised by the researcher.
Category
Behavior

2

Description
Intervention group: the warm Foot baths will perform for three consecutive nights for patients with 40 ° C water for 30 minutes, 1hour before bedtime. Legs up to 10 cm above the ankle will dip in a special plastic container. SMHSQ questionnaire and Beck Anxiety Inventory (BAI) questionnaire will be completed every day during the 7 to 8 am.
Category
Other

3

Description
Intervention group: Combination: The patients in the combined group are asked to first bath their feet in water for 30 minutes and then Perform relaxation for 20 minutes in accordance with the above mentioned protocols.
Category
Behavior

4

Description
Control group: In the control group, nothing will be done in 3 consecutive nights of intervention, but The SMHSQ questionnaire will be completed for three days and each day during 7 to 8 am.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee hospital
Full name of responsible person
Hoda Arianpour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Yasouj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Hoda Arianpour

Position
MS of Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

General data such as demographic variables and outcomes under study will be published.

When the data will become available and for how long

Get started 6 months after printing results

To whom data/document is available

All researchers working in academic and scientific institutions who want the results of the study will be allowed to receive the data

Under which criteria data/document could be used

Data can be used to enhance science and use results in research

From where data/document is obtainable

School of Nursing & Midwifery, Rashid Yasemi St, Vali Asr St,Tehran 00982143651000 nsahraea@gmail.com

What processes are involved for a request to access data/document

Once requested, the data will be delivered electronically or in person within one week.

Comments