Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment the effect of Bensons Relaxation technique on Pain, Anxiety, and Delirium of patients who underwent Open Heart Surgery

Protocol summary

Study aim

Overall Objective: determine of the effect of Benson relaxation on pain, anxiety and delirium of patients who undergoing open heart surgery. Specific objectives: Determine and compare the mean of pain, anxiety and delirium scores of patients before and after the intervention in both experimental and control groups. • Comparison of mean pain, anxiety and delirium scores of patients between the experimental and control groups before and after the intervention between the experimental and control groups.

Design

A clinical trial study with two groups of control and intervention, with parallel groups, double-blind, randomized, on 60 patients. The quadruple block method was used for randomization.

Settings and conduct

This study was performed on 60 patients who were candidates for coronary artery bypass graft surgery at Ghaem Hospital of Mashhad. Benson relaxation method was performed in the intervention group and no intervention was performed in the control group.

Participants/Inclusion and exclusion criteria

Age ranged (18 - 64 years), don't use of sedatives and anti-anxiety drugs, Having no mental illness, first experience of open heart surgery

Intervention groups

In the intervention group for Benson muscle relaxation, patients were asked to lie in bed for twenty minutes in the best position which they feel relaxed, and close their eyes. in this mood select a relaxing word (such as God, love, and ...), and start breathing and repeat this word in their minds, and at the same time relax their muscles from the tips of their toes and continue to the upper muscles of the body to fully expand all the muscles of the body. And maintain this state for twenty minutes. For the control group, only the routine actions of the ward were performed.

Main outcome variables

Benson relaxation method

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210903052365N1**
Registration date: **2022-01-28, 1400/11/08**
Registration timing: **prospective**

Last update: **2022-01-28, 1400/11/08**
Update count: **0**

Registration date

2022-01-28, 1400/11/08

Registrant information

Name

saeed vaghee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

vaghees@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment the effect of Bensons Relaxation technique on Pain, Anxiety, and Delirium of patients who underwent Open Heart Surgery

Public title
The effect of Benson relaxation on reducing pain, anxiety, and delirium of cardiac patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age ranged (18 - 64 years) Do not use sedatives and anti-anxiety drugs during research No drug abuse Do not take similar courses of muscle relaxation No mental illness confirmed by a psychiatrist No problems with muscle paralysis or musculoskeletal disorders Having informed consent to participate in the study
Exclusion criteria:
Age
From **18 years** old to **64 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were divided into experimental and control groups by randomization. In each training session, the names of all the people who had the inclusion criteria were written on a sheet of paper in a sealed envelopes, and half of them were selected by a person other than the researcher by lottery for training.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, the patients in the intervention group were selected and the intervention was performed, and then the control group was selected. The questionnaires were completed with the help of a researcher who was blind to division of patients into two groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
School of Nursing and Midwifery, Ibn Sina St., Doctor Crossroads, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2021-01-12, 1399/10/23
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.074

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R07.2
ICD-10 code description
Precordial pain

2

Description of health condition studied
Anixity
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

3

Description of health condition studied
Delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Pain
Timepoint
At 24, 48 and 72 hours after the intervention
Method of measurement
Visual Analgesic Scale

2

Description
Anxiety
Timepoint
At 24, 48 and 72 hours after the intervention
Method of measurement
Questionnaire

3

Description
Delirium
Timepoint
Before and after the intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group for Benson muscle relaxation, patients were asked to lie in bed for twenty minutes in the best position which they feel relaxed, and close their eyes. in this mood select a relaxing word (such as God, love, and ...), and start breathing and repeat this word in their minds, and at the same time relax their muscles from the tips of their toes and continue to the upper muscles of the body to fully expand all the muscles of the body, And maintain this state for twenty minutes.
Category
Treatment - Other

2

Description
Control group: No intervention was performed in the control group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital of Mashhad
Full name of responsible person
Ali Golchoobi Firouzjah
Street address
Faculty of Nursing and Midwifery, Ibn Sina St., University St., Mashhad, Iran
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golchoubia1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohamad Hossein Tafaghodi
Street address
Mashhad, Vakil Abad Blvd, University pa
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Postal code
9177948954
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Ali Golchoubi Firouzjah
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
Street address

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available