

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

Anxiety

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

City

Mashhad

Province

South Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1337

Email

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

Faculty of Nursing and Midwifery, Ibn Sina St.,
University Crossroads, Daneshgah St., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

golchoubi1@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Vaghee

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Ibn Sina St.,
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Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

Email

vaghees@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Vaghee

Position

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City

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Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

vaghees@mums.ac.ir

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