

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Effect of Benson's relaxation on anxiety and physiological parameters on candidate of open heart surgery patients in selected hospitals of AJA University Medical Science.

Protocol summary

Summary

This study is a clinical trial was performed on 90 patients undergoing open heart surgery. The main inclusion criteria included aged 20 to 70 years old; Absence of trouble hearing; Unfamiliarity with the same periods with Benson's relaxation in the experimental and control groups; Absence of musculoskeletal system disorder; The ability to communicate in Persian language; The ability to taking Benson's relaxation training; Absence of contraindications to control blood pressure and pulse of the right hand and The main exclusion criteria Included unwillingness to continue cooperation in the study at any time of the study. Data collection instruments included a demographic questionnaire, and the Spielberg's anxiety inventory. The patients were randomly assigned into two experimental and control groups. Anxiety levels in two groups the day before surgery measuring by questionnaire Spielberg's anxiety and then in the experimental group were trained Benson's relaxation. In the morning of surgery, Benson's relaxation were performed by the experimental group and then anxiety levels and physiological parameters control and evaluation in both groups about half an hour before was sent to the operating room. Finally data analyzed was performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520328N1**
Registration date: **2015-08-26, 1394/06/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-26, 1394/06/04

Registrant information

Name

Mahdi Malmir

Name of organization / entity

AJA University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 88028350

Email address

mahdimalmir@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

AJA University Medical Science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Benson's relaxation on anxiety and physiological parameters on candidate of open heart surgery patients in selected hospitals of AJA University Medical Science.

Public title

The Effect of Benson's relaxation on anxiety in candidate of open heart surgery patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Aged 20 to 70 years old; Absence of trouble hearing; Absence of psychiatric illness recognized; Not use sedative or anti-anxiety drugs except of the routine method; Not having with substance abuse; Unfamiliarity with the same periods with Benson's relaxation in the experimental and control groups; Absence of musculoskeletal system disorder; The ability to communicate in Persian language; The ability to taking Benson's relaxation training; Absence of contraindications to control blood pressure and pulse of the right hand. Exclusion criteria: Unwillingness to continue cooperation in the study at any time of the study.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

AJA University of Medical Science

Street address

Adjacent to Imam Reza (AS) Hospital, Martyr St.

Etemadzadeh, Tehran

City

Tehran

Postal code

Approval date

2014-09-27, 1393/07/05

Ethics committee reference number

9319

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2

Description of health condition studied

Chronic ischemic heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease Coronary (artery)

Primary outcomes

1

Description

anxiety

Timepoint

During two days

Method of measurement

Spielberg's anxiety inventory

2

Description

physiological parameters

Timepoint

During two days

Method of measurement

A stethoscope and sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Anxiety levels in two groups the day before surgery measuring by questionnaire Spielberg's anxiety and then in the experimental group were trained Benson's relaxation. In the morning of surgery, Benson's relaxation were performed by the experimental group and then anxiety levels and physiological parameters control and evaluation in both groups about half an hour before was sent to the operating room.

Category

Other

2

Description

In the control group routine care done.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected Hospital of AJA University of Medical Sciences (Hospital 502)

Full name of responsible person

Dr.Mohammad Ali Bayanfar

Street address

Intersection of Taleghani and Bahar Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AJA University of Medical Science

Full name of responsible person

Dr. Armin Zareian

Street address

Shariati Ave. Kaj St. Aja College of Nursing

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

AJA University of Medical Science

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

AJA University of Medical Sciences

Full name of responsible person

Mahdi Malmir

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work**Street address**

Aja College of Nursing

City

Tehran

Postal code**Phone**

+98 21 7750 0404

Fax**Email**

mahdimalmir@ajaums.ac.irmalmir65@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

AJA University of Medical Sciences

Full name of responsible person

Fatemeh Teimouri

Position

Mentor

Other areas of specialty/work**Street address**

AJA College of Nursing

City

Tehran

Postal code**Phone**

+98 21 7750 0404

Fax**Email**

fatemeh teimouri@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

AJA university of medical sciences

Full name of responsible person

Mahdi Malmir

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work**Street address**

AJA College of Nursing

City

Tehran

Postal code**Phone**

+98 21 7750 0404

Fax**Email**

mahdimalmir@ajaums.ac.irmalmir65@yahoo.com

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