

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of improving body awareness skills on anxiety, depression, and quality of life of patients after heart surgery in Bu Ali Hospital in Qazvin

Protocol summary

Study aim

Evaluation of the effectiveness of improving body awareness skills on anxiety, depression, and quality of life of patients after heart surgery

Design

Clinical trial with control group with parallel, randomized, phase 3 groups on 50 patients. A random number table was used for randomization.

Settings and conduct

This intervention takes place in the city of Qazvin. Patients who have undergone heart surgery are randomly divided into two nodes. Patients will be trained in bodybuilding exercises. These trainings are given to patients under the supervision of a psychiatrist and according to the training protocols of the World Health Organization. Before and one week after the interventions, the rate of depression and anxiety as well as the quality of life of patients are measured by special questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have undergone heart surgery, interest in participating in research and informed consent, full consciousness and having the necessary ability to participate in the study, age 18 to 65 years. Exclusion criteria: History of mental disorder based on DSM-5 diagnostic criteria, except depression, drug use and stimulants, mourning of loved ones during the last quarter.

Intervention groups

Intervention group: Patients in this group will be trained in bodybuilding exercises for six hours a week for two weeks. These trainings are given to patients under the supervision of a psychiatrist and according to the training protocols of the World Health Organization. Before and one week after the interventions, the rate of depression and anxiety as well as the quality of life of patients are measured by special questionnaires.

Main outcome variables

Anxiety score, Depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190404043159N2**

Registration date: **2020-10-02, 1399/07/11**

Registration timing: **prospective**

Last update: **2020-10-02, 1399/07/11**

Update count: **0**

Registration date

2020-10-02, 1399/07/11

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

sharbafchi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2020-11-04, 1399/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of improving body awareness skills on anxiety, depression, and quality of life of patients after heart surgery in Bu Ali Hospital in Qazvin

Public title
Improving body awareness skills and anxiety, depression, and quality of life

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have had heart surgery Interest in participating in research and informed consent Full consciousness and having the necessary ability to participate in the study Age 18 to 65 years
Exclusion criteria:
History of mental disorder based on DSM-5 diagnostic criteria except depression. Drugs or stimulants abuse Mourning of loved ones during the last three months.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.

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 Esfahan university of Medical sciences

Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City
Isfahan

Province
Isfahan

Postal code
813786615

Approval date
2019-07-20, 1398/04/29

Ethics committee reference number
IR.MUI.MED.REC.1398.211

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

2

Description of health condition studied
Depression

ICD-10 code
F06.31

ICD-10 code description
Mood disorder due to known physiological condition with depressive features

3

Description of health condition studied
Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety score

Timepoint
Before and one week after interventions

Method of measurement
By The Depression, Anxiety, and Stress Scale - 21 (DASS-21) questionnaire

2

Description
Depression score

Timepoint
Before and one week after interventions

Method of measurement

By The Depression, Anxiety, and Stress Scale – 21 (DASS-21) questionnaire

3

Description

Quality of life score

Timepoint

Before and one week after interventions

Method of measurement

MacNew Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will be trained in bodybuilding exercises for six hours a week for two weeks. These trainings are given to patients under the supervision of a psychiatrist and according to the training protocols of the World Health Organization. Before and one week after the interventions, the rate of depression and anxiety as well as the quality of life of patients are measured by special questionnaires.

Category

Treatment - Other

2

Description

Control group: For patients in this group, the rate of depression and anxiety as well as the quality of life of patients are measured by special questionnaires. Patients will not receive training. 1 week after the study, the rate of depression and anxiety as well as the quality of life of patients are measured twice by special questionnaires.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Mohammad Reza Sharbafchi

Street address

No. 22, Roshd St., Imam Khomeini Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

6774672561

Phone

+98 31 3668 0042

Email

sharbafchi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Fax

Email

haghjoo.sh@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Sharbafchi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
sharbafehi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohammad Reza Sharbafehi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
sharbafehi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohammad Reza Sharbafehi
Position
Assistant professor
Latest degree
Specialist

Other areas of specialty/work
Psychiatrics
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
sharbafehi@med.mui.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments