

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality in patients undergoing open heart surgery

Protocol summary

Study aim

The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality of patients undergoing open heart surgery

Design

A randomized, double-blind, parallel group, controlled clinical trial, For random assignment, each end-participant of the research is first given a code of 1 to 84(sample size) and then using R software and sample instruction, 42 code out of 84 codes will be selected as the intervention group and the rest of the numbers will represent the control group code.

Settings and conduct

The target population was all patients with open heart surgery who referred to Shiraz Kowsar Hospital. During the interview and if the consent is obtained, the presence or absence of depression in patients with the use of DISH tool and its severity is evaluated using the Beck Depression Instrument. If the illness did not have symptoms of depression in the initial interview with Beck or had partial depression, then a second interview would be done to her after 4 weeks of discharge. If the patient showed complete depression symptoms in the second interview, he / she will be randomly assigned to either test or control group.

Participants/Inclusion and exclusion criteria

The main entry conditions include the incidence of depression and sleep disorder after open heart surgery and the main incontinence conditions including the incidence of depression and sleep disorder before open heart surgery

Intervention groups

The intervention group: have some degree of depression and post-operative sleep disturbance, in addition to routine care at the treatment center, for whom CBT protocol will also be considered. The control group included those who, based on the tools used, developed some degree of depression and post-operative sleep disturbance and received only routine care in the

treatment center.

Main outcome variables

Depression, Sleep Disturbance

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20190717044252N1**

Registration date: **2019-11-10, 1398/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Elham Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 5484

Email address

ehosseini@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality in patients undergoing open heart surgery

Public title

The effect of Cognitive Behavioral Therapy (CBT) program on depression and sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to attend counseling sessions Minimum diploma education Age between 20 and 65 years Stay in shiraz Full vigilance and ability to speak Persian Physical and mental fitness required to answer questions Not attending other training courses at the same time Not having a specific psychiatric condition before surgery Having Depression After Heart Surgery Having a sleep disorder after heart surgery

Exclusion criteria:

The unwillingness of the subject to participate or continue to participate in the research Cases of other diseases, including malignancies or autoimmune disorders Facing specific mental crises before surgery Treated with sedative drugs before surgery

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

For random assignment, at first, each of the final participants will be given a sample of one to 84 (sample size), then using the software R and the sample command, 42 of the code are selected from 84 codes as the intervention group, and the remaining numbers represent The code will be the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The days of referral in the intervention group for counseling are different with the days of referral of patients in the control group.

Placebo

Not used

Assignment

Parallel

Other design features

The highlight of the above study is the implementation of a cognitive behavioral therapy program by a trained Nursing Specialist.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of the Faculty of Nursing and Midwifery and Rehabilitation of Tehran University

Street address

No. 29, 11 Ave., Shahidan Gerami Ave., Farhang Shahr Ave., Shiraz

City

Shiraz

Province

Fars

Postal code

7187665736

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.043

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode

2**Description of health condition studied**

Sleep Disorder

ICD-10 code

F51

ICD-10 code description

Nonorganic sleep disorders

Primary outcomes**1****Description**

Depression Score in Beck Questionnaire

Timepoint

The beginning of the study and the end of the intervention

Method of measurement

Beck Depression Inventory

2

Description

sleep disorder

Timepoint

The beginning of the study and the end of the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive behavioral intervention group or CBT. Intervention group includes those who have mild to moderate degrees of post-operative depression based on the tools used and will receive CBT protocol in addition to routine care at the treatment center. The CBT protocol will consist of 10 to 12 one-hour weekly sessions, when the patient is indicated, by a trained nurse and in an appropriate pre-embedded location. There will be interactions, discussions, assignments and feedback. Weekly focal points are as follows: Week One: Establish a therapeutic relationship, set a meeting schedule, identify problems objectively, and set treatment goals. Week 2: Increasing patient knowledge, activating behavioral functions, and problem solving techniques. Week 3-4: Identifying automatic thoughts, improving problem-solving skills, reducing ineffective cognitive processes on behavior. Week 5-6: Reconstructing automatic thoughts, identifying abilities, and learning self-treatment techniques. Weeks 7 to 8: Continue self-treatment and relapse prevention. Week 9 - 10: Training to improve self-care skills in the field of illness and to increase acceptable activity according to disease conditions, end Intervention and discontinuation of therapeutic relationship. In this intervention, two sessions were considered as floating to complete the questionnaire or if needed for a longer session and need to continue the intervention.

Category

Behavior

2

Description

Control group: The control group includes those who receive only routine post-cardiac care routine care. Routine and routine care, including routine medical and nursing follow-up after cardiac surgery and psychiatric evaluation of a patient by a psychiatrist only if necessary, and requesting a psychiatric consultation by the ICU cardiologist.cognitive intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz, Kowsar Hospital

Full name of responsible person

Elham Hosseini

Street address

Kowsar Hospital., Qasr-Dasht St., Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۸۷۷۹۵۹۶۱

Phone

+98 71 3614 1000

Email

elhamh765@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

MOHAMMAD ALI SAHRAIAN

Street address

Sina Hospital., Imam Khomeini Ave., Hasan Abad Sq., Tehran

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6670 6142

Fax

+98 21 6670 6141

Email

msahrai@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

+98 21 6105 4000

Email

e_navab100@hotmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elham Navab

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressFaculty of Nursing and Midwifery., Dr Mirkhani St.,
Tohid Square.,Tehran**City**

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

e_navab100@hotmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elham Navab

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressFaculty of Nursing and Midwifery., Dr Mirkhani St.,
Tohid Square.,Tehran**City**

Tehran

Province

Tehran

Postal code

1419733171

Phone**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elham Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street addressNo.29., 11Ave., Shahidan Gerami Ave., Farhang Shahr
Ave., Shiraz**City**

Shiraz

Province

Fars

Postal code

7187665736

Phone

+98 71 3631 5484

Fax**Email**

ehosseini@razi.tums.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