

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the supportive educational Nurse-led intervention on anxiety and sleep in patients before bypass grafting surgery

Protocol summary

Summary

The purpose of this study is to investigate the effect of supportive educational Nurse-led intervention on anxiety and sleep in patients before bypass grafting surgery. It's a randomized control trial investigation. Patients who are scheduled for bypass grafting surgery are subjected to this study. Total numbers of 160 eligible patients were categorized in to two groups: Control & Intervention groups. The Inclusion criteria were: having consent to participate, scheduled elective bypass grafting surgery, ability to speak Persian, having no sleep disorder before hospitalization (self-reported), having no mental disorder (self-reported). The Exclusion criteria were: reluctant to continue, having previous bypass grafting surgery, having both bypass grafting surgery and valve replacement or other surgery at the same time, occur any acute fatal hemodynamic condition or any problem which cancel the surgery. The first day of hospitalization, they should complete informed consent, demographic information; spielberger state anxiety and Groningen sleep quality scale. In control group, spielberger state anxiety is filled the night before the surgery and Groningen sleep quality scale is filled on the morning of the surgery. Intervention group perform supportive educational Nurse-led intervention during hospitalization before surgery. the supportive educational Nurse-led intervention consists of communicate with patient, give general information about surgery, encourage patient to talk about anxiety and its causes, introduce the stress management techniques such as Benson muscle relaxation, deep breathing, praying, guided imagery. Then they learn one of these techniques which the patient choose and practice it during the sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406154443N12**

Registration date: **2015-09-03, 1394/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-03, 1394/06/12

Registrant information

Name

Masoumeh Zakerimoghdam

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2015-03-11, 1393/12/20

Expected recruitment end date

2015-07-22, 1394/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the supportive educational Nurse-led intervention on anxiety and sleep in patients before bypass grafting surgery

Public title

The effect of nursing care on anxiety and sleep of patients before coronary artery bypass graft

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having consent to participate, scheduled elective bypass grafting surgery, ability to speak Persian, doesn't have any sleep disorder before hospitalization (self reported), doesn't have any mental disorder (self reported) Exclusion criteria: reluctant to continue, repeat surgery, having both bypass grafting surgery and valve replacement or other surgery at the same time, occur any acute fatal hemodynamic condition or any problem which cancel the surgery.

Age

From **20 years** old to **120 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Categorization of the patients is conducted by using random block. Lottery was used to select the starting block of the study and the first block was introduced as test group and after filling the block with 10 patients, the control block will be filled. This process will continue to get the desired number of patients in each group. Simultaneously, the sampling will take place in reverse order in the 2nd hospital.

Secondary Ids

empty

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

Ethics Committee of Tehran University of Medical Science

Street address

Ghods street, Keshavarz boulevard

City

Tehran

Postal code**Approval date**

2015-03-07, 1393/12/16

Ethics committee reference number

9111449018-142232

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

cardiovascular disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

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

Anxiety

Timepoint

first day of hospitalization, the night before the surgery

Method of measurement

spielberger state anxiety scale

2**Description**

sleep

Timepoint

first day of hospitalization, the morning of the surgery

Method of measurement

Groningen sleep quality scale

Secondary outcomes

empty

Intervention groups**1****Description**

In control group just will receive regular care (perform doctor's orders, check vital signs, give medication and preparation for surgery) without any intervention.

Category

Other

2**Description**

supportive educational Nurse-led intervention consists of 4 steps: 1- communicate with patient 2- give general information about surgery 3- encourage patient to talk about fear, anxiety and their causes 4- introduce stress management techniques such as Benson muscle relaxation, deep breathing, praying, guided imagery and learn one of the techniques which the patient choose and then practice it during the session.

Category

Other

Recruitment centers1**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person**Street address**

Nosrat St.

City

Tehran

2**Recruitment center****Name of recruitment center**

Shariati hospital

Full name of responsible person**Street address**

Jalal-e-Al-e-Ahmad Hwy.

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

vice chancellor for research, tehran university of medical science

Full name of responsible person

Dr. Masoud Younesian

Street address

Ghods street, Keshavarz Blvd., Central building of university, 6th floor

City

Tehran

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

Yes

Title of funding source

vice chancellor for research, tehran 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**

Tehran University of Medical Science

Full name of responsible person

Masoumeh Zakeri Moghadam

Position

Lecturer

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

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Postal code**Phone**

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Fax

Email
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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