Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity

Tehran University of Medical Sciences

Country

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Phone

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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 centers

1

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 sources

1

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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Person responsible for updating data

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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