Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of comfort- based nursing cares on their perception of nursing care behaviors and comfort level among patients undergoing open heart surgery

Protocol summary

Summary

This study is a randomized controlled clinical trial and research environment is intensive care unit at the Golestan heart center in the Kordkoy town. The aim of study is to determine the effects of comfort centered care on patients' comfort and patients' perception of nursing care behaviors in open-heart surgery patient. Sample size is determined through a pilot study. Then patients who are selected based on inclusion criteria will be randomly allocated to experimental and control groups. Randomization will be done through block randomization. Totally 70 patients will be enrolled. Interventions: intervention group will receive planned care including reflexotherapy and open heart surgery care education through face-to-face education and pamphlets and modification of environmental factors. All interventions will be done at a fixed time in each day during six consecutive days and patients will complete HCQ and CBI questionnaires 24 hour six days after surgery and intervention. Control group will receive only routine care. Inclusion criteria: being at the age of 25 to 60 years; the willingness to participate in the study; signing an informed consent; complete consciousness of the patient; not being emergency surgery, the ability to make a verbal communication; the ability to read and write; there are no scratches, scars, corn, infection or any loss and damage in the feet; no history of mental illness or addiction and absence of vision or hearing impairments; PTT in the range of 30 to 60. The main outcomes in this study are comfort level and its dimensions and patients' perception of care behaviors and its dimensions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032733153N1**
Registration date: **2017-04-16, 1396/01/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-16, 1396/01/27

Registrant information

Name

Fatemeh Sheikhy

Name of organization / entity

Birgand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3238 1410

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Birgand University of Medical Sciences and Investigator

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comfort- based nursing cares on their perception of nursing care behaviors and comfort level among patients undergoing open heart surgery

Public title
The effect of comfort- based nursing cares on the perception of care behaviors and comfort
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: being at the age of 25 to 60 years; the willingness to participate in the study; signing an informed consent; complete consciousness of the patient; not being emergency surgery, the ability to make a verbal communication; the ability to read and write; there are no scratches, scars, corn, infection or any loss and damage in the feet; no history of mental illness or addiction and absence of vision or hearing impairments; PTT in the range of 30 to 60.
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
allocate patients to permutation blocking manner to experimental and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birgand University of Medical Sciences
Street address
Birgand University of Medical Sciences; Ayatollah Ghaffari street; Birjand; South Khorasan
City
Birgand
Postal code
9717853577
Approval date
2017-01-02, 1395/10/13
Ethics committee reference number
IR.bums.REC.1395.232

Health conditions studied

1

Description of health condition studied
open heart surgery
ICD-10 code
I97.1
ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
Patients' perception of nursing care behaviors
Timepoint
24 hour after surgery and before intervention and six days after intervention
Method of measurement
Caring Behavior Inventory Questionnaire

2

Description
Comfort
Timepoint
24 hour after surgery and before intervention and six days after intervention
Method of measurement
Hospice comfort questionnaire

Secondary outcomes

1

Description
comfort Physical dimension
Timepoint
24 houre after surgery and before the intervention and after the intervention in Six days.
Method of measurement
score of Physical Dimension of comfort questionnaire

2

Description
comfort psycological dimension
Timepoint
24 houre after surgery and before the intervention and after the intervention in Six days.
Method of measurement
score of psycological Dimension of comfort questionnaire

3

Description
Comfort environmental dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention on sixth day.
Method of measurement
Score of environmental Dimension of comfort questionnaire

4

Description
comfort social dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention in Six days.
Method of measurement
score of social Dimension of comfort questionnaire

5

Description
Respect others dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention in Sixth day.
Method of measurement
score of Respect others dimension

6

Description
Assurance of human presence Dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention in Six days.
Method of measurement
Assurance of human presence Dimension score

7

Description
Positive Communication and attitude Dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention on Sixth days.
Method of measurement
Positive Communication and attitude Dimension score

8

Description
Knowledge and Professional skills dimension
Timepoint
24 houre after surgery and before the intervention and after the intervention in Six days.
Method of measurement
Knowledge and Professional skills dimension score

9

Description
Attention to others' experiences dimension
Timepoint
24 hour after surgery and before the intervention and after the intervention on sixth day.
Method of measurement
Attention to others' experiences dimension score

Intervention groups

1

Description
Intervention group: Interventions include modification of environmental lights, devices' alarm and personnel sounds and reflexothrapy in reflective chest point under the thumb of the left foot and cardiac surgery care training through face-to-face education and pamphlets. Interventions will be implemented during six consecutive days at 17 o'clock.
Category
Rehabilitation

2

Description
Control group will receive only routine care. Pamphlets will be given to patients on sixth day in order to comply with the ethical principles.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kordkoy Amiralmoomenin Hospital
Full name of responsible person
Dr.GholamAli Riaahy
Street address
Amiralmoomenin Hospital, Jangal street, Kordkoy, Golestan Province
City
Kordkoy

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Birgand University of Medical Sciences
Full name of responsible person
Shahnaz Tabiee
Street address
Birgand University of Medical Sciences; Ayatollah Ghaffari street; Birjand; South Khorasan
City
Birgand
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,Birgand University of Medical Sciences

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

Birgand University of Medical Sciences

Full name of responsible person

Fatemeh Sheikhy

Position

Master Student in Nursing

Other areas of specialty/work

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Faculty member

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Other areas of specialty/work

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ilia.sheikhy1364@gmail.com; Fa.sheikhy@bums.ac.ir; Fa.sheikhy@bums.ac.ir

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