Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of holistic nurse's intentional presence on the depression, stress and anxiety of the patients undergoing coronary artery bypass graft

Protocol summary

Summary

Objective: To determine The effect of holistic nurse’s intentional presence on depression, anxiety and stress in patients under coronary artery bypass surgery This study is a controlled clinical trial which was conducted in 1395 in Mashhad.80 patients undergoing coronary artery bypass surgery were divided randomly into two Intervention and control groups. In the intervention group in 4 sessions of 30 to 45 minutes intentional presence was carried out at three physical, psychological and therapeutic levels at the time of hospital admission (1 session), ICU (1 session), surgical ward (2 sessions). Anxiety and depression in patients was measured before the intervention and after the treatment sessions by DASS21 tool. Routine procedures were performed in the control group and they were given educational pamphlets. Data was analyzed by SPSS software as well as chi-square and analysis of covariance

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112925288N1**
Registration date: **2016-10-13, 1395/07/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-13, 1395/07/22

Registrant information

Name

Zeinab Khajian galoogahi

Name of organization / entity

Medical science of mashhad university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of holistic nurse's intentional presence on the depression, stress and anxiety of the patients undergoing coronary artery bypass graft

Public title

Effect of intentionality presence of Cardiac Artery Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria of study 1. Willingness to participate in the study 2. Age between 38 and 75 years 3. Having at least the literacy of writing and reading 4. Having an elective surgery 5. The ability to communicate with researcher 6. Lack of psychological disorders 7. Non- use of antipsychotic drugs 8. Candidate for coronary artery

bypasses graft (CABG) 9. Lack of drug addiction Exclusion criteria of study: 1. Refusing from continued participation in the study and collaboration with researcher 2. Incidence of physical disorders during the study (drainage that requires for operating room again) 3. Death of subject of study 4. Postoperative cognitive dysfunction (delirium, lack of knowledge of time, place, and person) 5. Late recovery and prolonged hospitalization (recovery after 6 hours or hospitalization more than 2 days in intensive care unit) 6. Heart surgery for the second time 7. Postoperative drug addiction

Age
From **38 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Mashhad University of Medical Sciences

Street address
Four ways PhD, School of Nursing and Midwifery, Mashhad Jarjani

City
Mashhad

Postal code

Approval date
2016-04-17, 1395/01/29

Ethics committee reference number
IR.MUMS.REC.1394.712

Health conditions studied

1

Description of health condition studied
Coronary artery disease

ICD-10 code
125.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
Anxiety

Timepoint
Before and then after intervention

Method of measurement
Dass21 scal and stressors

2

Description
Stress

Timepoint
Before and then after intervention

Method of measurement
Dass21 scal and stressors

3

Description
Depresion

Timepoint
Before and then after intervention

Method of measurement
Dass21 scal and stressors

Secondary outcomes

empty

Intervention groups

1

Description
In control group: In the beginning of patients' admission to open heart surgery ward, subjects' consent was obtained and their demographic information was obtained by a questionnaire examined their anxiety, stress, and depression and routine measures were taken for patients. In addition, educational pamphlets available in the ward along with educational pamphlets related to relation were provided for patents. During patient discharge, questionnaire assessing the anxiety, stress, and depression DASS 21 was completed again. In the control group, relaxation techniques and training to patients were performed trough educational pamphlets (Appendix 10) without the presence of a nurse (researcher), but measuring vital signs were measured and recorded during the four stages similar to experimental group.

Category
Treatment - Other

2

Description

Experimental group: intervention begins from patient hospitalization time in the open-heart surgery time. After introducing himself to patients, completing the demographic form and conscious consent of patient, and completing assessing the anxiety, stress and depression of patient by DASSS 21, researcher implemented the presence process at three levels of 1. Physical presence, 2. Mental presence and 3. Therapeutic presence. Accordingly, nurse will be able to select and use the best method for patients among the holistic methods based on unique investigation of each patient and determining the stressful resources, using strategies such as using and training relation or training the patient on unknowns, by relying on his specialized skill and knowledge, his nursing diagnoses (Table 3-1), and based on patient priority. Specifically, presence of nurse depends on individual characteristics of nurse, individual characteristics of client, characteristics shared in the communicative space of nurse-client, an appropriate environment to do communicative task, and performance decisions of nurse. The first session of intended presence in the open-heart surgery ward and before surgery was implemented. The second session was implemented after patient recovery in the intensive care unit and third and fourth sessions were implemented in the heart surgery ward. During nurse-client interaction, there are points the probable dose of presence. Specifically, relying on his clinical skill and his previous experiences in the presence process, nurse interprets the latent delicate signs and objective needs of the patient, and he deliberates and makes decision in the special moment on the most appropriate presence dose by considering environmental factors. On average, presence dose is determined based on patient's need in each shift and 30 to 45 minutes has been considered (Figure 3-10. If patient needed, number of therapeutic sessions and presence dose might increase. After therapeutic sessions of presence, on the patient discharge, patient complemented the questionnaire assessing the anxiety, stress, and depression DASS 21 again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Shariati Hospital

Full name of responsible person

Nahid aghebati

Street address

Vakil Abad Blvd. end-street Imam Reza1 (AS)

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr.Tafaghodi

Street address

Daneshgah street; Mashhad

City

Mashhad

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, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghedati

Position

Nursing Ph.D

Other areas of specialty/work

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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