

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effects of Holistic nursing care with the Therapeutic communication helping model approach on patients and their family satisfaction in cardiac care unit

Protocol summary

Study aim

Effects of Holistic nursing care with the therapeutic communication helping model approach on patients and their family satisfaction

Design

Two-group clinical trial with post-test

Settings and conduct

This study is a two groups clinical trial. 108 patients who were hospitalized in Mousvi hospital in Zanjan and their family members in 2017 that had entry criteria was participated in the study by simple sampling method. The 4-part tool was used: patients' satisfaction instrument, a 30-item questionnaire in Persian on satisfaction of family members of patients admitted in Intensive care units and an Interpersonal Communication Skills Scale (A.S.M.A). At first the control group received the usual nursing care then we held a 4-hour workshop in order to familiarize nurses with using therapeutic communication helping model. Before and after the workshop the level of nurses' communication skills were measured by ASMA. After that we started to allocate intervention group. The experimental group received Holistic-care from the moment of entering to the discharge of cardiac care unit and after implementing care program and at the end of the patient stay, the patient and their family member satisfaction in two groups was measured by using a modified form of satisfaction questionnaire. The data analysis was done by SPSS software, version 22 using descriptive and inferential statistics.

Participants/Inclusion and exclusion criteria

Patients and their family members who have entrance criteria: stay more than 3 days in CCU ward; being oriented; age > 18; able to communicate and like to attend in essay were allocated. Exit criteria: leave ward sooner than 3 days or do not like to continue.

Intervention groups

Patients hospitalized in CCU and their family members
Main outcome variables
satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120507009664N8**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Mitra Payami Bousari

Name of organization / entity

Zanjan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 24 3315 6962

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payami@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-01-20, 1395/11/01

Actual recruitment end date

2017-06-20, 1396/03/30

Trial completion date

empty

Scientific title

Effects of Holistic nursing care with the Therapeutic communication helping model approach on patients and their family satisfaction in cardiac care unit

Public title

Effects of Holistic nursing care with the Therapeutic communication helping model approach on patients and their family satisfaction in cardiac care unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

being hospitalize almost 3day; being orient; age more than 18; being able to communicate verbal or in verbal and like to take apart in.

Exclusion criteria:

being discharge or leave ward sooner than 3day or do not like take apart in essay

AgeFrom **18 years** old**Gender**

Both

Phase

1-2

Groups that have been masked*No information***Sample size**Target sample size: **108**Actual sample size reached: **108****Randomization (investigator's opinion)**

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences. Azadi blv,Iran

City

Zanjan

Province

Zanjan

Postal code

98 24 3314 8325

Approval date

2017-01-01, 1395/10/12

Ethics committee reference number

ZUMS.REC.1395-146

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

cardiac disease

ICD-10 code

I50

ICD-10 code description

Cardiac disease

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

satisfaction

Timepoint

In two periods of time

Method of measurement

questionnaire

Secondary outcomes

empty

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

Intervention group: The experimental group patients and their family received Holistic-care from the moment of entering to the discharge of cardiac care unite

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Cardiac Care Unite in Mousvi Hospital in Zanjan

Full name of responsible person

Parisa Jahangiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr.Korosh Amini
Street address
Vice Chancellor for Research and Technology, Second floor, Building No.1, The Central building of Zanjan University of Medical Sciences, Azadi Sq., Zanjan, Iran
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Person responsible for general inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Parisa Jahangiri
Position
Student
Latest degree
Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

En Effects of Holistic nursing care with the Therapeutic communication helping model approach on patients and their family satisfaction in cardiac care unit

When the data will become available and for how long

6 month

To whom data/document is available

Author

Under which criteria data/document could be used

By getting authors permission

From where data/document is obtainable

To Zanjan university

What processes are involved for a request to access data/document

Sending an email to author

Comments