Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of planned family member’s presence of coronary critical care inpatients on family member´s anxiety and their perception about nurses’ caring behavior

Protocol summary

Summary

The main objective: Determining the effect of planned family member’s presence of coronary critical care inpatients on family member´s anxiety and their perception about nurses’ caring behavior Type of research: Clinical trial Research population: Family member's of coronary critical care inpatients Research sample: The selected eligible first degree family member of patients Inclusion criteria: First degree family member; Age 18 to 60 years; Lack of known psychological disease; Lack of thyroid disease; No history of hospitalization in intensive care (the family member or the patient); Do not belong to health care team Exclusion criteria: Discontinue to participate in the study; Disturbing the ward discipline; Interference with patient care programs; Impossible continuous participation throughout the process of data collection; Dying the patient during the data collection process; The patient discharge or transfer to another department during the data collection process; Occurrence special events to the patient like CPR or intubation Method: This study is a clinical trial. Qualified samples will be selected by convenience sampling and randomly (toss a coin) divided into control and intervention groups. In intervention group, the presence of selected family member is planned. It means one of first degree family members of patient that is constant is selected according to patient's preference and she/he should have eligible criteria. The selected family member can be present in the ward twice per day for two days and 15 minutes in each turn. The family member is allowed to perform some patient's primary care such as dressing, washing face, eating, going patient to the bathroom, hair brushing,teeth brushing, etc. In the control group, family member can just visit the patient according to the policy of hospital that is a limited and strict schedule of visiting without any permission for doing any patient's care. The dependent variables are anxiety and perception of nurse's caring behavior which will evaluate by Spielberger's questionnaire and the caring behavior inventory (CBI-24), respectively. The questionnaires will be completed before intervention (at the first day of patient hospitalization) and after intervention (at the end of third day) in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727442N1**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name
Seyyedeh Halimeh Kamali
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 4208 7245
Email address
h-kamali@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date
2016-08-22, 1395/06/01
Expected recruitment end date
2017-03-20, 1395/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of planned family member’s presence of coronary critical care inpatients on family member’s anxiety and their perception about nurses’ caring behavior

Public title
The effect of family member’s presence of CCU patients on anxiety and perception's of family about nursing care
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: First degree family member; Age 18 to 60 years; Lack of known psychological disease; Lack of thyroid disease; No history of hospitalization in intensive care (the family member or the patient); Do not belong to health care team Exclusion criteria: Discontinue to participate in the study; Disturbing the ward discipline; Interference with patient care programs; Impossible continuous participation throughout the process of data collection; Dying the patient during the data collection process; The patient discharge or transfer to another department during the data collection process; Occurrence special events to the patient like CPR or intubation
Age
From **18 years** old to **60 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
Qualified samples will be selected by convenience sampling and randomly (toss a coin) divided into control and intervention groups

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran Univerity of Medical Sciences
Street address
Keshavarz Bluv., Qods St., Central Building of Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2016-05-07, 1395/02/18
Ethics committee reference number
IR.TUMS.REC.1395.2560

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease
ICD-10 code
100-199
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1

Description
Anxiety
Timepoint
Before intervention and at the end of third day
Method of measurement
Spielberger's state Anexiety Scale

2

Description
Perception of nurses’ caring behavior
Timepoint
Before intervention and at the end of third day
Method of measurement
Caring behavior inventory-24 items (CBI-24)

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, the presence of selected family member is planned. It means one of first degree family members of patient that is constant is selected according to patient's preference and she/he should have eligible criteria. The selected family member can be present in the ward twice per day for two days and 15 minutes in each turn. The family member is allowed to perform some patient's primary care such as dressing, washing face, eating, going patient to the bathroom, hair brushing,teeth brushing, etc.

Category
Other

2

Description
In the control group, family member can just visit the patient according to the policy of hospital that is a limited and strict schedule of visiting without any permission for doing any patient's care.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Seyyedeh Halimeh Kamali
Street address
City
Ghaemshahr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Yunesian
Street address
Keshavarz Bluv., Qods St., Central Building of Tehran University of Medical Sciences
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 of Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Seyyedeh Halimeh Kamali
Position
Nursing student
Other areas of specialty/work
Street address
Juibar St., 8th. Beheshti St., Saba Buiding
City
Ghaemshar
Postal code
Phone
+98 11 4208 7245
Fax
no fax
Email
h-kamali@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medhcal Science
Full name of responsible person
Dr. Masoomeh Imanipour
Position
PhD
Other areas of specialty/work
Street address
Tohid Sq., School of Nursing and Midwifery
City
Tehran
Postal code
Phone
+98 21 6105 4425
Fax
Email
m_imanipour@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity

Tehran University of Medical Science
Full name of responsible person
Seyyedeh Halimeh Kamali
Position
Nursing student
Other areas of specialty/work
Street address
City
Ghaemshahr
Postal code
Phone
+98 11 4208 7245
Fax
Email
h-kamali@razi.tums.ac.ir;
halimeh_kamali@yahoo.com
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