

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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)

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+98 11 4208 7245

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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

AgeFrom **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 Anxiety 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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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