Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of care with a human approach on anxiety and hopelessness of patients candidate for coronary angiography

Protocol summary

Study aim
Determining the effect of care with a human approach on the angiography patients' anxiety level and hopelessness

Design
Interventional study , Clinical trial with control group, parallel groups, consecutive non-probability sampling, without blinding, Sample size is 30 individuals in each group.

Settings and conduct
In this clinical trial, 60 patients candidates of angiography were selected non randomly consecutive and divided into two groups of control and intervention (30 subjects in each group). Data gathering tool was Personal and Clinical Questionnaire, Beck Anxiety Inventory(BAI) and Beck Hopelessness Scale (BHS). Anxiety and hopelessness questionnaire completed by participants at two occasions: two to three days before and the night before angiography.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-angiography for the first time. 2-Patients admitted for at least 2 to 3 days before angiography. 3-Age 40 and 75 years. 4-communicate verbally in Persian or Lori dialect. 5-Stability of the physical, mental and psychological state. Exclusion criteria: 1-Receiving corticosteroids, sedative medicines and anxiolytic drugs during 72 hours before the study. 2-History of depression and anxiety disorders. 3-The existence of crises affecting life over the past six months. 4-History of Heart Surgery, Thyroid Disorders and Epilepsy. 5-Emergency angiography

Intervention groups
the control group: will receive the usual or routine care. Routine control includes receiving medicine, sending laboratory tests, performing chest graph, shaving the catheter insertion place, etc. the intervention group:relationship-based care, based on a content developed according to the 10 carative factors of Watson's theory, is built two or three days before angiography in three sessions.The length of each session varies according to patients' needs.

Main outcome variables
Anxiety and Hopelessness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180612040074N1**
Registration date: **2019-03-07, 1397/12/16**
Registration timing: **retrospective**

Last update: **2019-03-07, 1397/12/16**
Update count: **0**

Registration date
2019-03-07, 1397/12/16

Registrant information

Name
Mojgan Khademi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3341 0592

Email address
khademi.m@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-26, 1397/04/05

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care with a human approach on anxiety and hopelessness of patients candidate for coronary angiography

Public title

The effect of care with a human approach on anxiety and hopelessness

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for the first angiography operation Patients admitted for at least 2 to 3 days before angiography Age between 40 and 75 years Ability to communicate verbally in Persian or Lori dialect Stability of physical, mental and psychological conditions

Exclusion criteria:

Receiving corticosteroids, sedative medications and anxiolytics such as propranolol 72 hours before the study History of depression and anxiety disorders Experiencing serious crisis during the previous six months (including the death of close relatives, suffering from life-threatening illnesses, or close relative's serious illnesses, etc.) History of heart surgery, thyroid disorders, epilepsy and respiratory distress . Emergency Angiography

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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

Ethics committee of Lorestan University of Medical Sciences

Street address

Integrated Lorestan Medical Sciences- opposite to the Kahrizak village- km 5 Road of Khorram Abad-Boroujerd

City

Khoramabad

Province

Lorestan

Postal code

6814993165

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.LUMS.REC.1397.035

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

Anxiety

Timepoint

Two to three days before angiography and the night before angiography before and after intervention

Method of measurement

Beck Anxiety Inventory

2

Description

Hopelessness

Timepoint

Two to three days before angiography and the night before angiography and before and after intervention

Method of measurement

Beck Hopelessness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: if the patient is in the intervention group, relationship-based care, based on a content developed according to the 10 carative factors of

Watson's theory, which is confirmed by Nursing Specialists, is built two or three days before angiography in three sessions (each day one session is scheduled). The length of each session varies according to patients' needs.

Category

Prevention

2

Description

Control group: if the patient is in the control group, she/he will receive the usual or routine care. Routine control includes receiving medicine, sending laboratory tests, performing chest graph, shaving the catheter insertion place, etc.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorramabad Hospital of Shahid Madani

Full name of responsible person

Dr. Gholamreza Beyranvand

Street address

Imam Hussein Square, Khorram Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mojtaba Khaksariyan

Street address

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mojkhaksar@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Fatemeh Malasadi

Position

Graduate student of Medical-Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work
Nursery
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Person responsible for updating data

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Fatemeh Malasadi
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The participant data file will remain confidential
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Intervention study protocol
When the data will become available and for how long
After the publication of the study protocol is available
To whom data/document is available
The study protocol is published
Under which criteria data/document could be used
The protocol can be used to use and use the theory
From where data/document is obtainable
The study protocol is published
What processes are involved for a request to access data/document
The study protocol is published
Comments
In this study, the study protocol is published.