Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

"The impact of environmental factors (sound, light, color) in waiting units on the physiological indices of anxiety in patients undergoing coronary angiography"

Protocol summary

Summary

Objectives: The aim of this study will to assess the impact of environmental factors (sound, light, color) in waiting units on the physiological indices of anxiety in patients undergoing coronary angiography. Design: In this clinical trial study, 200 hospitalized patients, for coronary angiography procedure, in waiting units of Khatam hospital in Zahedan, who are between the ages of 18 to 65 years, having no anxiety disorders, not drug addicted, no hearing and major visual impairment and being conscious, will randomly assign to 4 groups based on sealed envelopes: (i) control group; (ii): Intervention group 1(sound): patients in this unit, will listen to the natural sounds; (iii): Intervention group 2 (sound and light): in this unit, patients in addition to listening to the natural sounds, will use natural daylight; and (iv): Intervention group 3 (sound, light and color): in this unit, patients in addition to listening to the natural sounds and using natural daylight, the blue color will used for sorting their unit suites. Anxiety physiological indices of patients including systolic blood pressure, diastolic blood pressure, heart rate, and respiratory rate, will measured immediately after the arrival of patients to the units, as well as 30 and 60 min after that using portable monitors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110317197N2**
Registration date: **2016-11-14, 1395/08/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name
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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"The impact of environmental factors (sound, light, color) in waiting units on the physiological indices of anxiety in patients undergoing coronary angiography"

Public title

"The impact of environmental factors (sound, light, color) in waiting units on the physiological indices of anxiety in patients undergoing coronary angiography"

Purpose

Supportive

Inclusion/Exclusion criteria
The inclusion criteria: patients between the ages of 18 to 65 years who underwent coronary angiography for the first time; These patients had no hearing deficit and no major visual problem; no consumption of any sedative or anti-anxiety used; except a single dose of Oxazepam according to the prescription of physicians in the last 24 h; no addiction; no anxiety disorders and all samples had full consciousness and were not in critical condition. The exclusion criteria: If any sudden changes was observed in the physiological parameters of anxiety in the patients or their unwillingness to continue to cooperate, they were excluded from the study at any time they wanted.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
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
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Qods Street, Keshavarz Street, Tehran, Iran
City
Tehran
Postal code
Approval date
2016-11-01, 1395/08/11
Ethics committee reference number
IR.TUMS.FNM.REC.1395.917

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Anxiety
Timepoint
Immediately after the arrival to the units, as well as 30 and 60 min after that
Method of measurement
Monitoring of anxiety physiological indices

Secondary outcomes

1

Description
Hemodynamic changes
Timepoint
Immediately after the arrival to the units, as well as 30 and 60 min after that
Method of measurement
Monitoring of anxiety physiological indices

Intervention groups

1

Description
Control group: Samples of this group, according to hospital routine, will enter into a single-bed unit that has no window because it is located at the end of the waiting hall and its lighting is financed by the artificial light sources of the hall. In this unit, all appliances are white. It will explain to the patients that he/she would wait in this unit for about 60 min before being transferred to the angiography unit. Nurse will come immediately after the patient enter to this unit, as well as 30 and 60 min after that, for the checking of physiological indices, before being sent to the catheterization lab.
Category
Other

2

Description
Intervention group 1 (sound): This unit is along the previous unit and has similar physical conditions with it. But, a media player and a headphone will placed at the bedside. After a similar explanation to the patient by the researcher, patients will asked to select a natural sound according to their preferences from the list in media player. Thereafter, they will listen to it using headphones

until the end of 60 min; this will followed by their transfer to the angiography section.

Category

Other

3

Description

Intervention group 2 (sound, light): The characteristics of this unit is the same with the previous unit and the difference is that it has a window that opened to the courtyard of the hospital. Thus, the lightening of the unit will provided by natural daylight. Patients of this group will receive similar guidance with two other groups but they will also requested not to close the curtains and to allow the light shine in the unit.

Category

Other

4

Description

Intervention group 3 (sound, light, color): In this unit, in addition to the availability of media player and having the same size of window as the previous unit, the blue color will used for sorting the suites.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Angiography ward of Khatam Hospital

Full name of responsible person

Vahideh Pouyesh

Street address

Khatam Hospital- Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masood Younesian

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Tehran University of Medical Sciences, Qods Street, Keshavarz Street, Tehran, Iran

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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

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

Nursing and Midwifery school of Tehran University of Medical Sciences

Full name of responsible person

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Position

Master Sciences of Nursing

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