Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of virtual reality on anxiety and vital signs of patients during coronary angioplasty.

Protocol summary

Study aim
Aim of this study is the effect of virtual reality on anxiety and vital signs of patients during coronary angioplasty.

Design
This is a randomized controlled trial study. Patients who candidate for femoral angioplasty in the first time, appropriate consciousness and without motion sickness and life threatening conditions are assigned in two groups according to randomized block design. In intervention group, before femoral needling in angioplasty, virtual reality film are playing for 15 minutes that contain nature pictures and light music. In control group there is not any intervention. Patients anxiety are measured with spielberger questionnaire before and after the angioplasty.

Settings and conduct
This study is performed in Valiasr hospital in Qom city. Persons who is measured the patients anxiety are not aware of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18-80 years; appropriate consciousness; angioplasty through femoral artery. Exclusion criteria: History of angioplasty; life threatening conditions; motion sickness

Intervention groups
Intervention group: Playing virtual reality film related to nature and light music for 15 minutes during angioplasty before needle insertion to femoral artery. Control group: Routine interventions are performed during angioplasty.

Main outcome variables
Stat and trait anxiety score Blood pressure, Heart rate, Arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110514006481N13**
Registration date: **2020-11-10, 1399/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**
Update count: **0**

Registration date
2020-11-10, 1399/08/20

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual reality on anxiety and vital signs of patients during coronary angioplasty.

Public title
Effect of virtual reality on anxiety of patients during

angioplasty.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Consciousness appropriate to cooperate Angioplasty through femoral artery

Exclusion criteria:
History of angioplasty Life threatening conditions Motion sickness

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done using stratified permuted block randomization. Patients are divided into two strata of male and female. For each stratum, a separate random assignment continues to reach the sample size. For random assignment in each stratum, four blocks of (A, B), which include different states of test and control sequences (AABB, ABAB ...), are used. Block selection is done according to a random digits table.

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
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی سمنان

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Semnan university of medical sciences, Shahid Akhlaghi intersection, Basij Blvd.,Semnan, Iran.

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Approval date
2020-09-22, 1399/07/01

Ethics committee reference number
IR.SEMUMS.REC.1399.192

Health conditions studied

1

Description of health condition studied
Coronary artery disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Stat and trait anxiety

Timepoint
15 minutes before and 15 minutes before angioplasty

Method of measurement
Spielberger anxiety questionnaire

2

Description
Vital signs

Timepoint
15 minutes before, during and 10 minutes after angioplasty

Method of measurement
Ward monitor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Playing virtual reality contain pictures of nature and light music for 15 minutes during angioplasty.

Category
Prevention

2

Description
Control group: Routine intervention is performed during angioplasty.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person
Hamid Bahramian

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Semnan university of medical sciences, 5th Km of Damghan road, Semnan, Iran.

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Sponsors / Funding sources

1

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
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Position
Associate professor

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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
There is no more information.
Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be 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