

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

Country

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solli257@semums.ac.ir

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

Street address

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

City

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Province

Semnan

Postal code

3514799442

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
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Sponsors / Funding sources

1

Sponsor

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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

Mohsen Soleimani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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