

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

Protocol summary

Study aim

The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

Design

Two arm parallel group (intervention and control) randomized clinical trial, no blinded, daily simple random sampling method, sample size is 80 participants.

Settings and conduct

To create virtual reality in the intervention group, we will use a virtual reality headset, a mobile phone and headphones to play the sound. A video via a mobile phone will be played that can change the viewing angle of 360 degrees while changing the patient's head position. Its contents include relaxing landscapes such as nature, beach, sea, etc. The video will be played by mobile phone, before transporting the patient to the Cardiac Angiography Suite of Heshmat Educational Medical Center.

Participants/Inclusion and exclusion criteria

All patients aged 40 to 60 years old are candidates for angiography; No history of angiography; Lack of motion sickness; No severe audio and visual disability; Lack of psychiatric disease; Not wanting to continue the experimental sample; No symptoms of anxiety

Intervention groups

Intervention involves the implementation of virtual reality on mobile phone for intervention group. In the control group, virtual reality will not be implemented. The equivalent time playing virtual reality for the intervention group will be present in the control group. The researcher will be next to the participant and no action will be taken.

Main outcome variables

Heart rate; Respiratory rate; Blood pressure; Anxiety level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140515017693N3**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**

Update count: **0**

Registration date

2019-03-03, 1397/12/12

Registrant information

Name

Mohammad Reza Yeganeh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 5056

Email address

yeganeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Virtual Reality Distraction on Patient's Anxiety Before Coronary Angiography

Public title
Effect of Virtual Reality Distraction on Patient's Anxiety

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 40 to 60 years old candidated for angiography
Exclusion criteria:
History of Angiography Motion Sickness Intense Hearing and Visual Disability Psychiatric Diseases

Age
From **40 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
Sampling will be performed with daily simple random sampling method. First, on a piece of paper, the name of the "intervention group", and on an another one, the name of the "control group" will be written, and placed in a bowl. Then one of the colleagues who do not have a role in sampling will randomly draw a paper. Whatever the result, the first day of sampling will be assigned to that group; then the next day, the sampling will be assigned to the other group. In other words, in one day, samples of the intervention group, and the next day the control group will be collected. Each groups, which reach earlier to 40, sampling for the other group will continue in the same way at one-day intervals to complete the sampling process for that group.

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
Guilan University of Medical Sciences
Street address
Gillan - Rasht - Namjoo Street - opposite Azodi Stadium - Gilan University of Medical Sciences
City

Rasht
Province
Guilan
Postal code
65385-41446

Approval date
2018-12-31, 1397/10/10

Ethics committee reference number
IR.GUMS.REC.1397.369

Health conditions studied

1

Description of health condition studied
Anxiety in candidates for coronary angiography
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety Scale in Short Version of the Spielberger's Anxiety Measurement Scale
Timepoint
Measuring anxiety score before and after intervention
Method of measurement
Short Version of the Spielberger's Anxiety Measurement Scale

2

Description
Systolic and diastolic blood pressure
Timepoint
Measuring systolic and diastolic blood pressure before and after intervention
Method of measurement
Aneroid sphygmomanometer

3

Description
Heart rate in one minute
Timepoint
Counting heart rate in one minute before and after intervention
Method of measurement
A stopwatch of a digital watch

4

Description
Respiratory rate in one minute
Timepoint
Counting respiratory rate in one minute
Method of measurement
A stopwatch of a digital watch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention involves the implementation of virtual reality on mobile phone for intervention group. In the control group, virtual reality will not be implemented. To create virtual reality in the intervention group, we will use a virtual reality headset, a mobile phone and headphones to play the sound. A video via a mobile phone will be played that can change the viewing angle of 360 degrees while changing the patient's head position. Its contents include relaxing landscapes such as nature, beach, sea, etc. The video will be played by mobile phone, before transporting the patient to the Cardiac Angiography Suite. Sounds include soft music, birds singing and the sound of the waterfall. The duration of this video will be 5 minutes.

Category

Prevention

2

Description

Control group: In the control group, virtual reality will not be implemented. The equivalent time playing virtual reality for the intervention group will be present in the control group. The researcher will be next to the participant and no action will be taken.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Heart Dr Heshmat

Full name of responsible person

Mohammad Reza Yeganeh

Street address

15 Azar St, next to Management and Planning Organization

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Rasht

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Guilan

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Email

heshmat@gums.ac.ir

Web page address

<http://www.gums.ac.ir/heshmat>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

Opposite 17th Shahrivar Hospital, Shahid Siadati St., Namjou St.

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Province

Guilan

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4144666949

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Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Yeganeh

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing & Midwifery Faculty, Guilan University of Medical Sciences, Daneshjoo St., Shahid Beheshti A

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Yeganeh
Position
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Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Nursing & Midwifery Faculty, Guilan University of
Medical Sciences, Daneshjoo St., Shahid Beheshti
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Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Yeganeh
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Latest degree
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Other areas of specialty/work
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Phone
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yeganeh@gums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The table of final results of the variables in data form and after statistical analysis is sharable without the individual information of each sample.

When the data will become available and for how long

Reachable in 2019

To whom data/document is available

Researchers and students in academic and scientific institutions, people working in the industry

Under which criteria data/document could be used

A variety of statistical analyzes will be allowed on data.

From where data/document is obtainable

Guilan University of medical Sciences, Vice chancellor for research Corresponding author: Mohammad Reza Yeganeh Address: Faculty of Nursing & Midwifery, Daneshjou St., Martyr Beheshti Boulevard, Rasht +981333555058 info@gums.ac.ir

What processes are involved for a request to access data/document

After submitting the application, the application is examined at the research council and the individual can access the data for a maximum of two months.

Comments