Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 PlaningOrganization

City
Rasht

Province
Guilan

Postal code
4193955588

Phone
+98 13 3366 9064

Fax
+98 13 3366 8718

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
Opposite17th Shahrivar Hospital, Shahid Siadati St.,Namjou St.

City
Rasht

Province
Guilan

Postal code
4144666949

Phone
+98 13 3333 5821

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

City
Rasht

Province

Guilan

Postal code
416351873

Phone
+98 13 1555 5056

Fax
+98 13 1555 0097

Email
yeganeh@gums.ac.ir

Person responsible for scientific 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 Ave., Rasht

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 13 1555 5056

Fax

Email
yeganeh@gums.ac.ir

Web page address

Person responsible for updating data

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 Ave., Rasht

City
Rasht

Province
Guilan

Postal code
41469-39814

Phone
+98 13 1555 5056

Fax

Email
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