

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of using relaxation images based on Virtual Reality on anxiety and quality of sleep in patients in Cardiac Care Unit

Protocol summary

Study aim

Determining the effect of using virtual reality-based sedation images on the anxiety and quality of sleep of patients admitted to the Cardiac Care Unit.

Design

Clinical controlled trial, not blinded, randomized study, includes 60 patients in the cardiac care unit.

Settings and conduct

This study will be done at Shahid Modarres Hospital in Kashmar. The level of anxiety and quality of sleep in patients in the cardiac care unit by hospital sleep questionnaire, Verran and Snyder-Halpern and Eshpilberger anxiety questionnaire before and after the intervention will be examined and compared in two groups of intervention (virtual reality) and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30 and 60 years old; Consciousness; orientation to time and place; The absence of psychiatric disorders. Exclusion criteria: Addiction.

Intervention groups

Intervention group: Includes 30 patients in the cardiac care unit. During the three nights before bedtime, a high quality video of 15 minutes will be displayed as virtual reality headset. Control group: Include 30 patients who do not undergo any intervention.

Main outcome variables

Anxiety, Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180517039698N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Mozhgan Hesabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5523 4443

Email address

Hesabim2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using relaxation images based on Virtual Reality on anxiety and quality of sleep in patients in Cardiac Care Unit

Public title

The effect of Virtual Reality on anxiety and quality of sleep in patients in Cardiac Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
 Signing the informed consent sheet Age between 30 and 60 years old Consciousness Orientation to time and place
 Have no sleep disorders Have no visual and hearing problem The absence of psychiatric disorders
 Hospitalized patients with the clinical diagnosis of heart disease in intensive Cardiac Care Unit

Exclusion criteria:
 Addiction

Age
 From **30 years** old to **60 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
 In this research, the samples will be selected by targeted sampling from the research community (taking into account entry criteria) and they will be randomly assigned to two groups of control and test (virtual reality) using permutable blocks method. Each block contains 4 patients, as a result 15 arrangements are possible. In selection of blocks, table of randomizes numbers is used.

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

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.GMU.REC.1397.005

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

Sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Eshpilberger anxiety questioner

2

Description

Sleep quality

Timepoint

The night before and after intervention

Method of measurement

Verran and Snyder Halpern Sleep Scale

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Sphygmomanometer (mmHg)

2

Description

Diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Sphygmomanometer (mmHg)

Intervention groups

1

Description

Control group: During the three nights of stay in the ward only routine treatments will be carried out without any intervention by the researchers.

Category

N/A

2

Description

Intervention group: During the three nights of stay in the ward for this group of patients, in addition to usual care, before sleep a video of nature with high quality for 15 minutes will be played by virtual reality headset (Model Remax-RT-V03). The hospital sleep questionnaire, Verran and Snyder-Halpern and Eshpilberger anxiety questioner will be completed before and after the intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Modaress martyr hospital

Full name of responsible person

Mozhgan Hesabi

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Razi street, Kashmar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sajjadi

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mozhgan Hesabi

Position

Critical Care Nursing Graduate Student / Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Mossa Sajjadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available