Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 5523 4443

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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
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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dr.Sajjadi.sa@gmail.com
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
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Mozhgan Hesabi
Position
Critical Care Nursing Graduate Student / Nurse
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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