Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative investigation of virtual reality, music therapy and aromatherapy on anxiety in cardiac care unit patients

Protocol summary

Study aim
Comparison of the effect of virtual reality, music therapy and aromatherapy on the anxiety of patients hospitalized in CCU

Design
A controlled ,randomised,blinded, clinical trial with 3 parallel study groups designed of 100 patients

Settings and conduct
Place of the intervention is the CCU department of Imam Khomeini Hospital. Four groups of 25 people who are randomly divided are selected, all four groups complete the Spielberger questionnaire immediately before the intervention. After that, the intervention is carried out in the three intervention groups, and then after a 20-minute break after the intervention, all three intervention groups and the control group complete the Spielberger questionnaire again. And finally, the information obtained from the four groups are compared with each other.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: age being over 18 years؛ being aware of time, place and people; having consented and completed a written consent form; having a healthy sense of hearing; not being sensitive to specific smells, including perfume, cologne or a special flower; no respiratory problem; no history of mental illness, depression or anxiety that has been diagnosed by a psychiatrist and no history of a new crisis such as: death of a first degree relative or divorce.

Intervention groups
First Intervention group: Virtual reality, using special virtual reality glasses, they see relaxing images for 15 minutes Second Intervention group: The music group for 15 minutes of silent music under the title ((Soft silent mix)) downloaded from the site nicmusic.net Third Intervention group: The aromatherapy group also smells the essential oil of Bahar Naranj plant produced by Adonis Gol Daru company for 15 minutes. Control group: does not receive any intervention

Main outcome variables
Patient's anxiety score in Spielberger questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240609062060N1**
Registration date: **2024-09-18, 1403/06/28**
Registration timing: **prospective**

Last update: **2024-09-18, 1403/06/28**
Update count: **0**
Registration date
2024-09-18, 1403/06/28

Registrant information
Name
Abbas Rezaie
Name of organization / entity
Khomein University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 4622 4142
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rezaieemail1994@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-05, 1403/07/14
Expected recruitment end date
2024-11-10, 1403/08/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation of virtual reality, music therapy and aromatherapy on anxiety in cardiac care unit patients

Public title

Effect of virtual reality, music therapy and aromatherapy on anxiety in cardiac patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years of age Being aware of time, place and people Having informed consent and completing a written consent form Having a healthy sense of hearing Not being sensitive to specific smells, including the smell of perfume, cologne, or specific flowers Not having any Respiratory problems No history of mental illness, depression or anxiety that has been diagnosed by a psychiatrist No history of new crisis such as death of 1st degree relatives, divorce of self or parents in the last 6 months

Exclusion criteria:

Patient's refusal to continue participating in the study The virtual reality, music therapy or aromatherapy becomes unpleasant for the patient patient's condition becomes critical

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done based on the table of random numbers.In this way, in the beginning, all the research units were numbered, then the RandBetween function was used by Excel software,and between the number 1 and 100 ,random numbers were obtained,and then the first 25 random numbers in the first study group, the second 25 random numbers in the second study group ,the third 25 random numbers in the third study group and the fourth 25 random numbers are placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The research units are unaware of the type of intervention in other groups.The data analyst also has access to the raw data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Khomein Univercity of Medical Sciences

Street address

Azadi Blvd.,Khomein town

City

Khomein

Province

Markazi

Postal code

3881743364

Approval date

2024-08-31, 1403/06/10

Ethics committee reference number

IR.KHOMEIN.REC.1403.015

Health conditions studied

1

Description of health condition studied

Stress of patients Hospitalised in cardiac care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient's anxiety score in Spielberger questionnaire

Timepoint

Before the intervention and 20 minutes after the intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Virtual reality,including 25

patients after completing Spielberger questionary by using special virtual reality glasses, they see relaxing images for 15 minutes, and after 20 minutes break they complet the Spielberger questionary for the second time.

Category

Other

2

Description

Second Intervention group: The music group including 25 patients after completing Spielberger questionary for 15 minutes they listen to silent music under the title ((Soft silent mix)) downloaded from the site nicmusic.net and after 20 minutes break they complet the Spielberger questionary for the second time.

Category

Other

3

Description

Third Intervention group: The aromatherapy group including 25 patients after completing Spielberger questionary smell the essential oil of Bahar Naranj plant produced by Adonis Gol Daru company for 15 minutes.and after 20 minutes break they complet the Spielberger questionary for the second time.

Category

Other

4

Description

Control group: does not receive any intervention they complete the Spielberger questionnaire two times with 35 minutes interval

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Ramin Ronassi

Street address

Shahid beheshti Blvd, Khomein town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein Faculty of Medical Science

Full name of responsible person

Abbas Farahani

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khomein Faculty of Medical Science

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

Khomein University of Medical Sciences

Full name of responsible person

Abbas Rezaie

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact
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Position
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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