Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

The effect of virtual reality therapy on anxiety, comfort and indicators of pulmonary function after surgery in cancer patients

Protocol summary

Study aim
Determining the effect of virtual reality on anxiety, comfort and pulmonary function indicators of patients after surgery in cancer patients

Design
The present study is a randomized clinical trial study with a control group, phase 1, on 56 patients. The rand function of Excel software was used for randomization. This study will not do blinding due to the probe type. Study groups include control and intervention groups.

Settings and conduct
56 people will be selected with available sampling method from the surgery department of the Cancer Institute of Imam Khomeini Hospital who meet the study criteria and will be randomly divided into two control and intervention groups.

Participants/Inclusion and exclusion criteria
The research community of cancer patients admitted to the surgery department of the Cancer Institute of Imam Khomeini Hospital Complex who have undergone thoracic or abdominal surgery for 48 hours and need respiratory rehabilitation.

Intervention groups
The control group will receive the usual pulmonary rehabilitation interventions and the intervention group will receive virtual reality interventions for 15 to 30 minutes a day and for five days a week in two weeks, in addition to the usual pulmonary rehabilitation interventions. On each day of the intervention, only one of the mentioned scenarios is shown to the patients, and the next scenario is shown in the next turn.

Main outcome variables
FEV1, FVC, anxiety, comfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220829055821N1**
Registration date: **2022-11-18, 1401/08/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-18, 1401/08/27**
Update count: **0**

Registration date
2022-11-18, 1401/08/27

Registrant information

Name
Nasim Aminaie
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6105 4317
Email address
n-aminaie@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual reality therapy on anxiety, comfort and indicators of pulmonary function after surgery in cancer patients

Public title

The effect of virtual reality on lung rehabilitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A patient diagnosed with cancer and 48 hours have passed since his/her chest or abdominal surgery Having a written order for pulmonary rehabilitation Awareness and awareness of time and place Willingness to participate in the study

Exclusion criteria:

Having hearing and vision disorders Having tuberculosis, pneumonia and other inflammatory respiratory diseases Having a history of heart disease Having lung cancer or lung metastasis Having diseases and injuries that disrupt the function of the musculoskeletal system Having a history of epilepsy, dizziness Having cognitive disorders (based on self-report)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the numbers 1 to 56 are written on separate papers, and then by lottery, each of the randomly selected samples is assigned a number from 1 to 56, and then the even numbers in a group and number Individuals are placed in another group. Then, similarly, one of the groups is randomly selected as the control group and the other group as the intervention 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

school of Nursing and Midwifery & school of Rehabilitation - Tehran University of Medical Sciences

Street address

Tawheed Square, Dr. Mirkhani St. (East Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-07-11, 1401/04/20

Ethics committee reference number

IR.TUMS.FNM.REC.1401.042

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

FEV١ - The maximum amount of air that a person can exhale with full force and power in the first second after maximum inhalation.

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days after the start of the study

Method of measurement

In order to check the lung function of patients, the amount of lung function indicators including FEV1 and FVC of patients 48 hours after chest or abdominal surgery will be checked using breathing test. The breath test will be performed at the breath test center of Imam Khomeini Hospital Complex (RA) and the patients will be transferred to this center at the beginning of the study and then 2 weeks after the start of the study and will return to their ward after the breath test.

2

Description

FVC - The total amount of air exhaled during the FEV test

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days after the start of the study

Method of measurement

In order to check the lung function of patients, the amount of lung function indicators including FEV1 and FVC of patients 48 hours after chest or abdominal surgery will be checked using breathing test. The breath test will be performed at the breath test center of Imam Khomeini Hospital Complex (RA) and the patients will be transferred to this center at the beginning of the study and then 2 weeks after the start of the study and will return to their ward after the breath test.

Secondary outcomes

1

Description

anxiety - A behavioral response such as fear, panic, worry, fatigue, and discomfort occurs when a person feels unsafe following an undefined danger or unknown threat.

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days after the start of the study

Method of measurement

Situational Anxiety Questionnaire (STAI)

2

Description

Comfort - a multi-dimensional and complex concept and means hope, strength, encouragement and freeing the patient from sadness and problems. In other words, comfort is a person's immediate experience of feeling strong and more than the absence of pain.

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days after the start of the study

Method of measurement

Kolkaba's General Comfort Questionnaire (GCQ)

Intervention groups

1

Description

Intervention group: In addition to the routine pulmonary rehabilitation interventions, the intervention group will also receive virtual reality interventions. The routine pulmonary rehabilitation interventions of the ward are in the form of teaching breathing exercises and chest physiotherapy by the nurse to the patient and his companion, and if necessary, requesting the advice of a physiotherapist and performing breathing exercises in the ward by the physiotherapist. The virtual reality intervention will be done by using SHINECON VR virtual reality glasses with a headset connected to it and showing the scenario of biking in the mountains and canoeing in the lake with visual and auditory stimulation. A mobile phone will be placed inside this device and the scenario playing on the mobile phone will be displayed to the patient in 3D. This device has a sensor to find the direction of head movement and has the ability to create a field of vision of 90 to 100 degrees. The weight of this device is 410 grams, which reaches 576 grams with the phone inside, and it will be placed on the patients' heads. Both scenarios will be reviewed and approved by the surgeon of the research team to ensure suitability for patients and simulating the real environment. On each day of the intervention, only one of the named scenarios is shown to the patients, and the next scenario is shown in the next turn. Patients in the intervention group will receive this intervention in the afternoon and at the patient's preferred time in a sitting position in their room or examination room for 15 to 30 minutes a day and for five days a week in two weeks. During the entire duration of the virtual reality intervention, the members of the research team and the doctor will be present with the patient, so that if the patient does not tolerate the intervention process for any reason, or in case of violent movements and the possibility of damage to the patient and his connections, the intervention will be stopped immediately. be made The data collection tool will be Kolkaba General Comfort Questionnaire (GCQ), Situational Anxiety Questionnaire (STAI) and Demographic Information Questionnaire. In order to check the lung function of patients, the amount of lung function indicators including FEV1 and FVC of patients 48 hours after chest or abdominal surgery will be checked using breathing test. The breath test will be performed at the breath test center of Imam Khomeini Hospital Complex (RA) and the patients will be transferred to this center at the beginning of the study and then 2 weeks after the start of the study and will return to their ward after the breath test. Before starting the interventions for the first time, the mentioned questionnaires will be completed by the patients, or if the patient is unable to read and write, or the patient is unable to speak, the researcher will read the questions in an expressive and understandable voice for the patient and The patient is asked to announce the desired option or point to the desired option with his finger and then the researcher records the answers. Then the usual pulmonary rehabilitation exercises will be performed for both groups and virtual reality exercises for the intervention group. Immediately 2 weeks after the start of the interventions, in order to measure the effectiveness of the pulmonary rehabilitation and the intervention, the FEV1 and FVC levels will be checked again using the breath test from both groups and Kolkaba's general comfort questionnaires. Situational Anxiety Questionnaire (STAI) will be completed again by the patients of both groups in the mentioned ways.

Category

Rehabilitation

2

Description

Control group: Control group: The control group will receive routine pulmonary rehabilitation interventions of the ward. The routine pulmonary rehabilitation interventions of the ward are in the form of teaching breathing exercises and chest physiotherapy by the nurse to the patient and his companion, and if necessary, requesting the advice of a physiotherapist and performing breathing exercises in the ward by the physiotherapist. The data collection tool will be Kolkaba General Comfort Questionnaire (GCQ), Situational Anxiety Questionnaire (STAI) and Demographic Information Questionnaire. In order to check the lung function of patients, the amount of lung function indicators including FEV1 and FVC of patients 48 hours after chest or abdominal surgery will be checked using breathing test. The breath test will be performed at the breath test center of Imam Khomeini Hospital Complex (RA) and the patients will be transferred to this center at the beginning of the study and then 2 weeks after the start of the study and will return to their ward after the breath test. Before starting the interventions for the first

time, the mentioned questionnaires will be completed by the patients, or if the patient is unable to read and write, or the patient is unable to speak, the researcher will read the questions in an expressive and understandable voice for the patient and The patient is asked to announce the desired option or point to the desired option with his finger and then the researcher records the answers. Then the usual pulmonary rehabilitation exercises will be performed for both groups and virtual reality exercises for the intervention group. Immediately 2 weeks after the start of the interventions, in order to measure the effectiveness of the pulmonary rehabilitation and the intervention, the FEV1 and FVC levels will be checked again using the breath test from both groups and Kolkaba's general comfort questionnaires. Situational Anxiety Questionnaire (STAI) will be completed again by the patients of both groups in the mentioned ways.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Nasim Aminaie Chatroodi
Street address
the end of Keshavarz Boulevard, Dr. Gharib Street; Imam Khomeini Hospital Complex
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/#

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
16 Azar St., 16 Azar St., Enghelab Square, Tehran University Central Organization
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 8889 6696
Email
tumspr@tums.ac.ir
Web page address
http://tums.ac.ir/

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nasim Aminaie Chatroodi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
61054317
Email
n-aminaie@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nasim Aminaie Chatroodi
Position
Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
61054317
Email
n-aminaie@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nasim Aminaie Chatroodi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
61054317
Email
n-aminaie@sina.tums.ac.ir

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