Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Guided visualization on Calming and Improving the Blood Oxygen Level of Chronic Obstructive Pulmonary Disease Patients Under Non-invasive Mechanical Ventilation

Protocol summary

Study aim
Reducing the anxiety of COPD patients under ventilation with a non-invasive mask and improving physiological conditions

Design
A semi-experimental study using Altman's nomogram, the required sample size is 27 people in each group, and considering a ten percent sample drop, 70 people are selected in each group, and then coding is done from number 1 to 70, and sixty are selected by lottery. People are chosen from among them

Settings and conduct
Sampling location of all ICUs of Baqiyatollah Hospital in Tehran; all patients with non-invasive ventilation conditions; audio file is played for a minute for patients while wearing a mask, and physiological conditions and anxiety are controlled. The same routine is performed for control patients..

Participants/Inclusion and exclusion criteria
Having COPD requires high pressure oxygen therapy Patients with mechanical ventilation with a non-invasive mask Age between 15 and 65 years Having healthy hearing and full consciousness Not having nervous and mental diseases Not taking sedatives and sleeping pills

Intervention groups
A mask is established for the patient and mechanical ventilation is established. And after thirty minutes, blood oxygen levels and physiological conditions including; Heart rate, breathing rate and restlessness level of the patient according to RASS criteria; Then, for twenty minutes of relaxation with the help of an audio file and headphones, the same routine procedures are performed for the control group.

Main outcome variables
Reducing anxiety and improving the physiological conditions of patients under ventilation with a non-invasive method

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240103060598N1**
Registration date: **2024-04-04, 1403/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-04, 1403/01/16**
Update count: **0**

Registration date
2024-04-04, 1403/01/16

Registrant information

Name
javad jamalreza

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 935 8173

Email address
javadjjamalreza@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Guided visualization on Calming and Improving the Blood Oxygen Level of Chronic Obstructive Pulmonary Disease Patients Under Non-invasive Mechanical Ventilation

Public title
The Effect of Guided visualization on Calming and Improving the Blood Oxygen Level of Chronic Obstructive Pulmonary Disease Patients Under Non-invasive Mechanical Ventilation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having COPD Needs high pressure oxygen therapy- Patients with mechanical ventilation with a non-invasive mask- Age between 15 and 65 years old Having healthy hearing and full consciousness Not having nervous and mental diseases- Not taking sedatives and sleeping pills

Exclusion criteria:
Invasive mechanical ventilation Repentance or decreased level of consciousness of the patient during the study Use of sedative drugs Unwillingness to continue research

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **27**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Altman's nomogram, the required sample size of 27 people in each group was estimated, which was studied by considering ten percent dropout of 30 people in each group. The initial screening was done based on the entry and exit criteria, 70 people were selected and then from Numbers 1 to 70 are coded and sixty patients are selected by lottery and again these sixty patients are listed from number one to sixty using a table of random numbers.

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
Baqiyatullah-ul-Azam (A.J.) Medical Education Center (Ethics in Research Committee)

Street address
Tehran - Quds town (west) - between South Flamak and Zarafshan, Simai Iran St. - Central Headquarters of Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City
tehran

Province
Tehran

Postal code
1435916471

Approval date
2023-12-11, 1402/09/20

Ethics committee reference number
IR.BMSU.BAQ.REC.1402.084

Health conditions studied

1

Description of health condition studied
Congestive respiratory diseases

ICD-10 code
J44

ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
Reducing the anxiety of patients undergoing non-invasive ventilation

Timepoint
Restlessness level control - physiological conditions when using a non-invasive mask before listening to the file and half an hour after listening to the file

Method of measurement
Use of rass criteria - pulse oximeter and pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The intervention group used an audio file with headphones based on Benson's relaxation technique for 30 minutes while using a non-invasive mask and repeated up to one hour if needed and

controlling the level of anxiety with the rass criterion as well as controlling the physiological conditions such as heart rate, blood pressure of the patient before And after the audio file

Category

Other

2

Description

Control group: The control group uses a non-invasive mask alone, as per the department's protocol, and before and during the use of the mask, the blood oxygen level, vital signs and anxiety level of the patient will be controlled with rass criteria

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah Hospital, Tehran, ICU departments

Full name of responsible person

Javad Jamalreza

Street address

Tehran, Vanak Square, Molla Sadra St., Sheikh Bahai St., Baqiyatullah University

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5256

Fax

+98 21 8755 5253

Email

R.bmsu@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abolfazl Rahimi

Street address

Tehran, Vanak Square, Molla Sadra St., Sheikh Bahai St., Baqiyatullah University.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5256

Email

R.bmsu@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Javad Jamalreza

Position

Master's Student of Special Nursing Care

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Pirouzi Blvd., 20 Alizadeh Haft, No. 14, Unit 1

City

Mashhad

Province

Razavi Khorasan

Postal code

9177974865

Phone

+98 915 935 8173

Email

javadjjamalreza@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abolfazl Rahimi

Position

Supervisor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address
Baqiyatullah University, Sheikh Bahai St., Mulla Sadra St., Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 5256
Email
fazel123@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Javad Jamalreza
Position
The Presenter
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
20 Alizadeh, 20 Pirouzi Blvd., Plate 14, Unit 1
City
Mashhad
Province
Razavi Khorasan
Postal code
9177974865
Phone
+98 915 935 8173
Email
javadjjamalreza@gmail.com

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