Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effect of music therapy on respiratory comfort, anxiety and depression during non-invasive ventilation in patients with covid-19 in Hospital

Protocol summary

Study aim
Evaluating the effect of music therapy on respiratory comfort, anxiety and depression during non-invasive ventilation in patients with covid-19 in Hospital

Design
Clinical trial with control group, with parallel, randomized, phase groups on 64 patients. Lottery is used for randomization.

Settings and conduct
In patients admitted to the intensive care unit of Covid-19 patients, the intervention includes 30 minutes of relaxing music. In the control group, all cases will be repeated, with the difference that only headphones will be used, without playing any music. Before and after these procedures, the patient's level of respiratory comfort, anxiety and depression will be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Conscious patients with Covid-19 undergoing non-invasive ventilation for the first time. No hearing problem

Intervention groups
The patient's respiratory comfort, anxiety and depression are measured before the intervention in the intervention and control groups and then the intervention includes 30 minutes of relaxing music, for patients in the intervention group for days on non-invasive ventilation daily and the first half hour Non-invasive ventilation will be broadcast with headphones. After the intervention, the patient's respiratory comfort, anxiety and depression will be measured. In the control group, all cases will be repeated, with the difference that only headphones (to prevent the influence of other sounds and influential factors) will be used without playing any music.

Main outcome variables
respiratory comfort, anxiety، depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171002036498N5**
Registration date: **2021-08-04, 1400/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-04, 1400/05/13**
Update count: **0**

Registration date
2021-08-04, 1400/05/13

Registrant information

Name
Ali Akbari

Name of organization / entity
Medical Sciences of Rafsanjan University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effect of music therapy on respiratory comfort, anxiety and depression during non-invasive ventilation in patients with covid-19 in Hospital

Public title
Evaluating the effect of music therapy on respiratory comfort, anxiety and depression during non-invasive ventilation in patients with covid-19 in Hospital

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Covid-19 undergoing non-invasive ventilation for the first time Patient consciousness Having written consent to enter the research No hearing loss or any inability to listen to music Absence of specific mental illness or use of neuropsychiatric drugs Absence of acute emotional stress in the last 6 months Age limit 20 to 65 years

Exclusion criteria:
Patient reluctance and satisfaction at any stage of the research Death or early discharge (before the end of the research intervention) Occurrence of an incident that makes it difficult to continue the intervention

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, research samples are selected based on inclusion criteria and available methods. The samples are then placed in each of the two groups using random classification by Minimization method. In this method, classes are first selected based on important research variables (gender and severity of depression). Then the first samples are placed randomly (tap, line) in one of the two groups. For the following samples, the sum of the samples in each group is considered and the sample is assigned to the group that has a smaller sum.

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 Rafsanjan University of Medical Sciences

Street address
No. 1, modares Blvd

City
Rafsanjan

Province
Kerman

Postal code
7718796755

Approval date
2021-07-19, 1400/04/28

Ethics committee reference number
IR.RUMS.REC.1400.076

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
In this study, breathing comfort refers to the score that patients give to their breathing comfort from a scale of ten centimeters. Grade 0: No breathing comfort and score 10: Maximum breathing comfort

Timepoint
Before and after the intervention

Method of measurement
Ten-centimeter ruler scale. HADS(Hospital Anxiety and Depression Scale)

Secondary outcomes

1

Description
Anxiety

Timepoint
Before and after the intervention

Method of measurement
Hospital Anxiety and Depression SCALE

2

Description

Depression

Timepoint

Before and after the intervention

Method of measurement

Hospital Anxiety and Depression SCALE

Intervention groups

1

Description

Intervention group: The intervention consists of 30 minutes of relaxing music. For patients in the intervention group, for days on non-invasive ventilation, it will be played daily with headphones for the first half hour of non-invasive ventilation. The patient's respiratory rate, anxiety and depression will be measured before the intervention in the intervention and control groups, and after the intervention, the patient's respiratory rate, anxiety and depression will be measured.

Category

N/A

2

Description

Control group: In the control group, all cases will be repeated, with the difference that only headphones (to prevent the impact of other sounds and influential factors) will be used without playing any music, and the level of respiratory comfort, anxiety and depression will be checked in the same way. The selected music is taken from other researches, including the number one piece of Dr. Arendstein's collection of works called Aramesh in Roya. This piece lasts about 30 minutes and is a calm and monotonous piece that is relaxing and without much excitement. The headphones used will be GBL and MBR-XB100VT, and the instrument used to measure anxiety and depression is the HADS instrument, and the numerical scale of the ruler is zero to ten.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebn-Abitaleb hospital

Full name of responsible person

Ali Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Akbari

Position

instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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