

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

Country

Iran (Islamic Republic of)

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+98 34 3425 5900

Email address

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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