

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of selected music-therapy on anxiety severity quantity and some indicators physiological of patients acute respiratory failure covid-19 undergoing non-invasive mechanical ventilation

Protocol summary

Study aim

Effects of selected music-therapy on anxiety severity quantity and some indicators physiological of patients acute respiratory failure covid-19 undergoing non-invasive mechanical ventilation

Design

Clinical trial with parallel control group, randomized, single center trial, Sample size 90 people (3 groups of 30 people) .

Settings and conduct

Babol Rohani Hospital

Participants/Inclusion and exclusion criteria

Patients with acute respiratory failure with Covid-19; Connection to non-invasive mechanical ventilation using face or nose-mouth masks; Awareness to the extent that there is the ability to communicate and answer questions; Interested in listening to music; Stable hemodynamic status without the use of vasoactive drugs; 24 hours have passed since admission to the ICU; Positional anxiety score should be 40 and higher.

Intervention groups

Intervention group 1: For each patient under non-invasive mask ventilation, he chooses 5 types of non-verbal soothing music based on his taste and plays for 20 minutes in the evening, using a headphone when no intervention is performed. Before and after the music is over, the physiological condition and vital signs and severity of the situational anxiety are measured again. Intervention group 2: For 20 minutes, a headphone is inserted when no care or treatment intervention is performed for the patient. but the player is turned off and nothing is played to the patient. Control group: The same routine interventions are performed and no additional interventions are performed.

Main outcome variables

Illness severity; Duration of admission to the ICU; The severity of anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N69**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **prospective**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-12-01, 1401/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of selected music-therapy on anxiety severity quantity and some indicators physiological of patients acute respiratory failure covid-19 undergoing non-invasive mechanical ventilation

Public title

Effects of selected music therapy on anxiety severity quantity of patients acute respiratory failure covid-19

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute respiratory failure with Covid-19
Connection to non-invasive mechanical ventilation using face or nose-mouth masks
Awareness to the extent that there is the ability to communicate and answer questions
Interested in listening to music. Stable hemodynamic status without the use of vasoactive drugs 24 hours have passed since admission to the ICU. Positional anxiety score should be 40 and higher.

Exclusion criteria:

Drug addiction
Existence of hearing impairment
Dangerous cardiac arrhythmia
Receive narcotics and sedatives 6 hours before the study
Existence of pain while studying

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

We will construct 6 blocks in ABC, ACB, BAC, BCA, CAB, and CBA using three blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 30 units of 3 blocks will be selected so that we consider having 30 people in the group (A), 30 people in the group (B) and 30 people in the group (C). Therefore, we will do block randomization.

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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.SEMUMS.REC.1400.121

Health conditions studied

1

Description of health condition studied

Coronavirus

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Illness severity

Timepoint

Before and after the intervention

Method of measurement

APACHE II disease severity classification system

2

Description

Duration of admission to the ICU

Timepoint

From the beginning of entry until discharge from the ICU

Method of measurement

Number of days in the ICU

3

Description

The severity of anxiety

Timepoint

Before and after the intervention

Method of measurement

Spielberger test anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: For each patient under non-invasive mask ventilation, he chooses 5 types of non-verbal soothing music based on his taste and plays for 20 minutes in the evening, using a headphone when no intervention is performed. Before and after the music is over, the physiological condition and vital signs and severity of the situational anxiety are measured again.

Category

Treatment - Devices

2

Description

Intervention group 2: For 20 minutes, a headphone is inserted when no care or treatment intervention is performed for the patient. but the player is turned off and nothing is played to the patient.

Category

Treatment - Devices

3

Description

Control group: The same routine interventions are performed and no additional interventions are performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Mohammadreza Asgari

Street address

Rouhani Hospital, Ganj Afrooz St., University Square, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh Ehsani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available