Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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
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Rouhani Hospital, Ganj Afrooz St., University Square, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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?
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
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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