Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Music therapy on ventilation criteria of patients undergoing mechanical ventilation

Protocol summary

Summary

Introduction: The goal of this research was studying the effect of music therapy on ventilatory criteria of patients under mechanical ventilation hospitalized in special wards and using music therapy as a complementary medicine. Complications of patients under mechanical ventilation are so much and considerable. One of the factors by recovery of which the separation from ventilator take place is ventilation criteria. Nursing, using music therapy, in case of reducing stress and anxiety, can cause ventilatory criteria and wening from mechanical ventilation tool. Materials and Methods: The present research took place with two group clinical trial method in intensive care unit of Hazrat Rasoul Akram Hospital. In this research 70 patients were chosen by random sampling methodology and divided in two 35-person intervention and control groups. For intervention group relaxing music therapy was played with headphone for 30 minutes once in the morning and once in the afternoon each day. For control group headphone was used without music in two turns each for 30 minutes. In both groups ventilation criteria of respiratory rate , peak airway pressure, minute ventilation, tidal volume and the amount of spo2 were recorded.

General information

Acronym

music and ventilation

IRCT registration information

IRCT registration number: **IRCT201411304443N16**
Registration date: **2015-05-07, 1394/02/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-07, 1394/02/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Music therapy on ventilation criteria of patients undergoing mechanical ventilation

Public title

music therapy and mechanical ventilation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 and under 70 years, under respiratory support with ventilator and with modes of CPAP, PSV, SIMV, maximum number of mandatory breathing apparatus Was 10, Tracheal intubation or Tracheostomy, staying under mechanical ventilation for

more than 24 hours, the Glasgow score above 7, the acute physiology score or APACHE II less than 20, no hearing problems, Hemodynamically stable condition including heart rate under 130 beats per minutes and systolic blood pressure above 90 mm Hg. Exclusion criteria: Having COPD and ARDS, discharge; sever hemodynamic impairment, the patient's unwillingness to participate in the study, the death of patient

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Tehran University of Medical Sciences

Street address
Office building of Tehran University of medical Science, Keshavarz St, Tehran.

City
tehran

Postal code

Approval date
2014-10-18, 1393/07/26

Ethics committee reference number
93/130/1708/ص

Health conditions studied

1

Description of health condition studied
patients undergoing mechanical ventilation

ICD-10 code
j95.0 , j9

ICD-10 code description
Chronic respiratory failure, Acute respiratory failure

Primary outcomes

1

Description
peak airway presser

Timepoint
30 minutes in morning and 30 minutes in evening

Method of measurement
Seen from the ventilator monitor and recorded in H2O cm

2

Description
tidal volume

Timepoint
30 minutes in morning and 30 minutes in evening

Method of measurement
Seen from the ventilator monitor and recorded in ml

3

Description
respiratory rate

Timepoint
30 minutes in morning and 30 minutes in evening

Method of measurement
Seen from the ventilator monitor and recorded in terms of the number per minute

4

Description
minute ventilation

Timepoint
30 minutes in morning and 30 minutes in evening

Method of measurement
Seen from the ventilator monitor and recorded in ml

5

Description
spo2

Timepoint
30 minutes in morning and 30 minutes in evening

Method of measurement
From pulse oximeter monitor in percentile

Secondary outcomes

1

Description
respiratori rate- spo2-peak airway presser-tv-mv

Timepoint
Time zero and ten and twenty and thirty minutes after the start of Music Therapy

Method of measurement
by using ventilator monitorig

Intervention groups

1

Description
In control group, the headphone was also used to prevent the annoying noises and patients were evaluated twice for one day that the duration of each one was 30 minutes between 9:30-10 AM and 16-16:30 PM. Restrictions imposed were same as intervention group. As the intervention group, all reparatory parameters and other variables were also measured in control group.
Category
Other

2

Description
In intervention group, instrumental music was played by headphone twice for one day that the duration of each one was 30 minutes between 9:30-10 AM and 16-16:30 PM. The music used in the study was track 1 of Arnd Stein's masterwork, namely Peace in Dream. This track is about 30 minutes. We chose the evening and morning to intervention, because of minimal medical interventions in these times. The researcher was present during the intervention. The respiratory parameters were recorded from the monitor at specified times. And during the study in intervention group, other nonemergency nursing interventions were stopped. The time for recording the respiratory parameters was defined as follows: before using the headphone and playing the music as 0, 10 minutes after playing music as 10, 20 minutes after playing music as 20, 30 minutes after playing music as 30; and all parameters were recorded from monitor of ventilator.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
rasol akram hospital
Full name of responsible person
masoomeh zakeri moghadam
Street address
Hazrat Rasoul Akram hospital,Niyayesh St, Sattarkhan St, Tehran.
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Sponsors / Funding sources

1

Sponsor
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Tehran University of Medical Sciences
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masume zakeri moghadam
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tohid square
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tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty