

Music therapy during mechanical ventilation in the intensive care unit

Submission date 29/06/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients hospitalized in the Intensive Care Unit (ICU) frequently need assistance for breathing, including mechanical ventilation (MV). MV is a procedure in which a tube is inserted in the throat of the patient, through which air flows and thus patients do not have to breathe on their own. While VM is essential for helping patients recover and guarantee survival, it can also be stressful and produce anxiety. This study aims at understanding if music therapy can be helpful in reducing anxiety in these patients, but also to test the feasibility of conducting a study and providing interventions for this population.

Who can participate?

Patients who are hospitalized, and currently receiving VM, are conscious, able to fill out short questionnaires, and are willing to participate.

What does the study involve?

Patients are randomly assigned to either live music-assisted relaxation sessions, sessions including listening to their favorite pre-recorded music, or a control group that receives standard care only.

What are the possible benefits and risks of participating?

Both live music and recorded-music listening have been shown to reduce anxiety and improve wellbeing in patients receiving VM. No adverse effects of these interventions have been reported previously, but potentially, music can also be unpleasant or unwanted at times. Asking patients if music is currently appreciated can help to reduce these risks.

Where is the study run from?

This study takes place in a high-complex hospital in Bogotá, the capital of Colombia.

When is the study starting and how long is it expected to run for?

March 2021 to March 2023

Who is funding the study?

This research is supported by the Vice Presidency of Research by the Fundación Universitaria de

Ciencias de la Salud, Bogotá, Colombia, via the Institutional Research Committee on December 17th 2021 - Acta No. 08 de 2021.

Who is the main contact?

1. Mark Ettenberger, PhD, mark.ettenberger@gmx.at
2. Sandra Milena Hernandez-Zambrano, smhernandez3@fucsalud.edu.co

Contact information

Type(s)

Principal Investigator

Contact name

Dr Mark Ettenberger

ORCID ID

<http://orcid.org/0000-0002-2706-6822>

Contact details

Calle 92 No 18-62

Bogota

Colombia

110221

+57 3112847635

mark.ettenberger@gmx.at

Type(s)

Scientific

Contact name

Prof Sandra Milena Hernandez-Zambrano

ORCID ID

<http://orcid.org/0000-0001-5504-3065>

Contact details

Cra. 54#67A-80

Bogotá

Colombia

-

None provided

smhernandez3@fucsalud.edu.co

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effect of MUsic Therapy on short-term psychological and physiological outcomes in Mechanically Ventilated patients: a randomized clinical pilot study (MUT-MV)

Acronym

MUT-MV

Study objectives

Music therapy during mechanical ventilation helps patients reduce anxiety levels

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/04/2021, Ethics Committee for Research with Human Subjects of the Hospital San Jose-Fundación Universitaria de Ciencias de la Salud (Carrera 54 No.67A - 80, Bogota, 111211, Colombia; +57 (601) 3538100 3550; vicerrectoriainvestigaciones@fucsalud.edu.co), ref: (CEISH) 0183-2021

Study design

Single-site randomized controlled three-arm pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life, Treatment, Safety, Efficacy

Participant information sheet

Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied

Anxiety in patients receiving mechanical ventilation

Interventions

This study is a single-site randomized controlled pilot study with three arms. Patients are randomized (1:1) using random numbers in Excel to intervention group 1, intervention group 2, or control group. All patients signed informed consent. Blinding of data collection and data analysis is guaranteed. Due to the nature of the intervention (music therapy), blinding patients and music therapists is not possible. A maximum of four interventions (one intervention daily) will be carried out from the day of the signing of the informed consent until the fourth intervention or the first extubation of the participant. Duration of the intervention: between 25-30 minutes.

Intervention Group 1: Music-Assisted Relaxation (MAR)

MAR is a music therapy technique that includes listening to live music, combined with guided relaxation and/or the use of imagery. First, the patient is asked to close his/her eyes or focus on a fixed point on the ceiling or wall. Then a verbal introduction is given, focusing on generating body awareness. In the next step, a mental image is introduced (for example, sitting on a beach watching the waves of the ocean, imagining a personalized safe and comfortable place). The patient is then asked to let himself/herself be guided by the music while concentrating on the imagery. Once the music had finished, the patient is asked to become aware again.

Intervention group 2: Patient-preferred Therapeutic Music Listening (PTML)

The use of pre-recorded music is a frequent resource in both music therapy and music medicine interventions. In music therapy, listening to music is based on an initial assessment and patient preferences, and takes place in the context of a therapeutic relationship. In this sense, the music is shared between the patient and the music therapist but is also guided by the patient's associations with the music. The music therapist maintains an active listening approach during the session and can verbally intervene to elaborate on the emotions, sensations, and thoughts that may arise from the music. In the first step, the patient is asked to identify music that he/she associated with a state of calmness, relaxation, and well-being, either using a script board or with yes/no questions. If the patient could not identify any specific songs or genres, the music therapist will use a pre-selection of music that meets the characteristics of anxiolytic music (long and soft tones, no fixed rhythm, simple melodies, consonant harmonies). In the next step, a wireless speaker and a tablet are used to play back the music. The music therapist is present during the session and guided the patient's continuous selection of music until the session ended.

Control group: Standard Care (CA)

In the control group, the participants did not receive any intervention in addition to their conventional treatment. However, environmental control (avoiding non-emergency medical procedures and keeping the room door closed) is recommended during measurements.

Intervention Type

Behavioural

Primary outcome measure

Anxiety measure using the Spanish 6-item version of the State-trait Anxiety Inventory (STAI-E6) at baseline (after signing the informed consent) and after each intervention

Secondary outcome measures

1. Perceived pain intensity by the patient measured using a Visual Analogue Scale (VAS) from 0-10 at baseline (after signing the informed consent) and after each intervention
2. Resilience measured using the Brief Resilience Scale (BRS) containing 6 items rated on a 5-point Likert scale at baseline (after signing the informed consent) and after the second, third,

and last intervention

3. Agitation/Delirium measured using the Confusion Assessment Method in the ICU (CAM-ICU) and Richmond Agitation Sedation Scale (RASS) at baseline (after signing the informed consent) and after each intervention

4. Vital signs including heart rate, respiratory rate, oxygen saturation, and blood pressure measured using routine patient monitoring before and after the intervention

5. Days of mechanical ventilation measured using patient records and calculated as follows: day of the first extubation – day of intubation = days of MV, at one timepoint

6. Extubation success including the number of failed extubations and/or necessary re-intubations measured using patient records at one timepoint

7. Days in the ICU measured using patient records, calculated as follows: date of discharge – date of admission = days in the ICU, at one timepoint

Overall study start date

01/03/2021

Completion date

30/03/2023

Eligibility

Key inclusion criteria

1. Aged older than 18 years

2. Mechanical ventilation hospitalized in the ICU

3. Alert and mentally competent (Richmond Agitation Sedation Scale between -1 and +1)

4. The expectation of being mechanically ventilated for more than 3 days from the moment of signing the informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

15

Total final enrolment

23

Key exclusion criteria

1. Confirmed bilateral hearing loss

2. Delirium or disorders of consciousness

3. Known psychiatric disorders

- 4. Cognitive disabilities
- 5. Known addictions to psychoactive substances

Date of first enrolment

07/03/2022

Date of final enrolment

11/07/2022

Locations

Countries of recruitment

Colombia

Study participating centre

Sociedad de Cirugía Hospital de San José

Calle 10 N° 18-75.

Bogota

Colombia

114111

Sponsor information

Organisation

Fundación Universitaria de Ciencias de la Salud

Sponsor details

Cra. 54 #67a-80

Bogota

Colombia

1112111

+57 (601) 4375401

vicerectoriainvestigaciones@fucsalud.edu.co

Sponsor type

University/education

Website

<https://www.fucsalud.edu.co>

ROR

<https://ror.org/02yr3f298>

Funder(s)

Funder type

University/education

Funder Name

Vicerectoría de Investigación FUCS

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/10/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the principal investigator, Mark Ettenberger, mark.ettenberger@gmx.at

The type of data that will be shared is raw data, which will be made available upon request in an Excel file including pre- and post-intervention measurements, medical data, and socio-demographic data as long as the anonymity of participants can be guaranteed. Timing for availability is after the publication of the main result. Informed consent to participate in the study was obtained. Data has been anonymized using participant coding.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/03/2024	24/09/2024	Yes	No