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Music therapy during mechanical ventilation in the intensive care unit

Submission date
29/06/2023

Recruitment status
No longer recruiting

Registration date
05/07/2023

Overall study status
Completed

Last Edited
24/09/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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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

Primary study design
Interventional

Study design
Single-site randomized controlled three-arm pilot study

Study type(s)
Quality of life, Treatment, Safety, Efficacy

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(s)
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

Key secondary outcome(s)
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/Delirum measured using the Confusion Assessment Method in the ICU (CAM-ICU) and Richmond Agitation Sedation Scale 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Sponsor information

Organisation
Fundación Universitaria de Ciencias de la Salud

ROR
https://ror.org/02yr3f298

Funder(s)

Funder type
University/education

Funder Name
Vicerectoría de Investigación FUCS

Results and Publications

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