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Effect of music therapy during endotracheal suctioning

Submission date
18/12/2023

Recruitment status
No longer recruiting

Registration date
29/12/2023

Overall study status
Completed

Last Edited
28/12/2023

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Endotracheal tube suctioning, where a tube is used to clear the airways, is an unpleasant and painful invasive practice that affects the comfort level of the patient. Music therapy has a positive effect on physiological parameters in patients receiving mechanical ventilation therapy in the intensive care unit. This study evaluates the effect of music therapy on the pain that occurs during the endotracheal suctioning procedure in patients who have undergone orotracheal intubation followed up in the intensive care unit.

Who can participate?
Patients aged between 18 and 99 years old who are hospitalized in the intensive care unit and have been orotracheally intubated

What does the study involve?
Researchers want to see if listening to music could help patients in the ICU when they undergo endotracheal suctioning. The researchers will gather information using various forms and scales to understand how the patients are doing.

For the music part, they picked Turkish Folk Music because most patients were 60 years old or older and were from certain regions in Turkey. They got help from a music expert to create a playlist.

They randomly split the patients into two groups: one group listened to music during the procedure, and the other didn't. They talked to the families of the patients, explained the study, and got their permission. They collected information about the patients before the procedure.

During the study, they played music for one group while doing the suctioning procedure, and the other group didn't get any music. They closely watched how the patients felt and their vital signs at different times during the study. After that, they switched the groups, so everyone got a turn with and without music during the procedure. They made sure not to do anything painful to the patients for an hour before the suctioning procedure.

What are the possible benefits and risks of participating?
Aspiration is the process of sucking mucus and other liquids out of the body with a vacuum device that works with negative pressure. It is a short-term painful procedure. This procedure creates a feeling of pain in the patient for about 15 - 20 seconds. It is of great importance for nurses to evaluate pain before and after painful procedures such as aspiration. Patients will receive quality care when their pain is evaluated and the possibility of suffering from complications will be minimized. Music therapy application will be used in pain management during this research. In the majority of studies in recent years, it has been stated that music played to intensive care patients for 20-30 minutes has a positive effect on reducing the pain of patients.
Patient's aspiration will be applied twice, with and without music therapy. During both applications, the patient's state of consciousness, fever, pulse, blood pressure, SpO2 values, parameters on the respirator, and pain level will be checked, and if a change in their general condition is detected, the aspiration process will be terminated immediately. (This is an acceptable and described complication of standardized ETT suctioning procedure).
In addition, music therapy will be applied with headphones. This practice may pose a risk of infection for patients, and to prevent this, it is planned to provide individual headphones for each patient.

Where is the study run from?
Acıbadem University (Turkey)

When is the study starting and how long is it expected to run for?
December 2018 to June 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Assoc. Prof. Esra Ugur, eugur1@gmail.com

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of the effect of music therapy applied to intensive care patients on pain during endotracheal suctioning

Acronym
EOMTDES

Study objectives
Music therapy has a positive effect on the pain that occurs during the endotracheal suctioning procedure in patients followed up as orotracheal intubation in the intensive care unit.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2019, Acibadem University and Acibadem Health Institutions Medical Research Ethics Committee (Kayisdagi Cad. No:32 Atasehir, Istanbul, 34752, Türkiye; +90 216 500 4308; atadek@acibadem.edu.tr), ref: 2019-1/16

Study design
Quasi-experimental with a single-group pre-post-test design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
The effect of music therapy application on the pain during the endotracheal suctioning procedure in patients followed up in the intensive care unit as orotracheal intubated.

Interventions
In this study, the researchers are evaluating the impact of music therapy on pain experienced during the endotracheal suctioning procedure among patients who have undergone orotracheal intubation and are being monitored in the intensive care unit (ICU). The study comprises 46 patients who meet the inclusion criteria, and the number of participants is determined based on power analysis and potential data losses. Various assessment tools, including the Patient Diagnosis and Follow-up Form, Glasgow Coma Scale (GCS), Richmond Agitation and Sedation Scale (RASS), and Intensive Care Pain Observation Scale (CPOT), are employed to collect study data.

For the preparation of music therapy material, Turkish Folk Music is chosen considering the cultural background of the patients, who are mainly individuals aged 60 and above from Central and Eastern Anatolian provinces. The selection of songs is guided by a faculty member in the musicology department, and a playlist is created for the musical intervention.

The randomization process involves assigning sequence numbers to all patients and dividing them into two groups: one with music therapy (n=23) and the other without (n=23), based on numbers generated from a random numbers table. Patient relatives are informed about the study protocol, and consent is obtained before the procedure. Patient identification and follow-up forms are completed for consenting patients.

During the endotracheal suctioning procedure, music therapy is applied to one group, while the other group receives no intervention. The musical therapy begins at the start of the study protocol and concludes at the end. Both groups are monitored for pain, agitation/sedation levels, consciousness, and hemodynamic parameters at the 1st, 30th, and 40th minutes of the study while on mechanical ventilation in the ICU. The endotracheal suctioning procedure is conducted in the 30th minute of the study for both groups. Subsequently, the groups are interchanged, and the next suctioning procedure is repeated: the music therapy group undergoes the procedure without music, and the non-music group receives the procedure with music therapy. Notably, no painful stimuli are administered to the patients one hour before the endotracheal suctioning procedure.

Data will be collected with the Patient Diagnosis and Follow-up Form and analyzed with NCSS 2007 Statistical Software. In addition to descriptive statistical methods, paired one-way analysis of variance, Newman Keuls multiple comparison tests, paired t-test, Friedman Test, Dunn's multiple comparison tests, Wilcoxon test, chi-square test, Mc Nemar's and Stuart-Maxwell test were used to evaluate the data.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using the Intensive Care Pain Observation Scale (CPOT) at 1, 30 and 40 minutes into the procedure

Key secondary outcome(s))
The following secondary outcome measures are assessed 1, 30 and 40 minutes into the procedure:
1. Physiological parameters including blood pressure, pulse rate, breathing and oxygen saturation of the blood (SpO2) measured using standard methods
2. Consciousness of patients measured using the Glasgow Coma Scale (GCS)
3. Sedation level of the patients measured using the Richmond Agitation and Sedation Scale (RASS)

Completion date
30/06/2019

Eligibility

Key inclusion criteria

1. Need for endotracheal suctioning
2. The FiO2 value in the ventilator is below 100%
3. Stability of hemodynamic parameters
4. No painful procedure has been applied until the last 1 hour before the suctioning
5. Procedure and not has been received narcotic or opioid-derived medical treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Patients who underwent tracheostomy
2. Unable to perform endotracheal suctioning (oral/jaw/face trauma)
3. Affected intracranial pressure
4. Administered neuromuscular blocking medication less than 6 hours before suctioning
5. Hearing problems

Date of first enrolment
01/02/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Türkiye

Study participating centre
Camlica Erdem Hospital
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Sponsor information

Organisation
Acıbadem University

ROR
https://ror.org/01rp2a061

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data that underlie the results reported in this article, after deidentification, (text, tables, figures, and appendices) will be available upon request from Assoc. prof. Esra Ugur, RN, PhD, eugur1@gmail.com, after the results article is published. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes