

Effect of music therapy during endotracheal suctioning

Submission date 18/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/12/2023	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Acibadem 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

Type(s)

Public, Scientific

Contact name

Prof Esra Ugur

ORCID ID

<http://orcid.org/0000-0002-2119-6175>

Contact details

Acibadem University Kayisdagi Cad. No:32 Atasehir

Istanbul

Türkiye

34752

+90 216 5004164

eugur1@gmail.com

Type(s)

Principal Investigator

Contact name

Ms Sebnem Akbas

ORCID ID

<http://orcid.org/0000-0003-2098-9322>

Contact details

Alemdağ Cad. Sezer Sok. No: 3-5 Ümraniye
Istanbul
Türkiye
34794
+90 543 5696571
krcsebnem@gmail.com

Type(s)

Public, Scientific

Contact name

Prof Esra Ugur

Contact details

Acibadem University Kayisdagi Cad. No:32 Atasehir
Istanbul
Türkiye
34752
+90 216 5004164
esra.ugur@acibadem.edu.tr

Type(s)

Principal Investigator

Contact name

Ms Sebnem Akbas

Contact details

Alemdağ Cad. Sezer Sok. No: 3-5 Ümraniye
Istanbul
Türkiye
34794
+90 543 5696571
sebnem.akbas@erdemhastahanesi.com.tr

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

13/12/2018

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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Both

Target number of participants

38

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

Kisikli, Alemdag Yanyolu No:36 Uskudar

Istanbul

Türkiye

34692

Sponsor information

Organisation

Acibadem University

Sponsor details

Kayisdagi Cad. No:32 Atasehir

Istanbul

Türkiye

344752

+90 500 0000

info@acibadem.edu.tr

Sponsor type

University/education

Website

<https://www.acibadem.edu.tr/>

ROR

<https://ror.org/01rp2a061>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

30/06/2024

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