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Effect of music therapy in mitigating anxiety and enhancing satisfaction in eldery patients undergoing lower limbs orthopedic surgery under intravertebral anesthesia

Submission date
26/03/2024

Recruitment status
No longer recruiting

Registration date
02/04/2024

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This research examines how music therapy can help reduce feelings of worry and improve overall happiness for older patients who are having surgery on their lower limbs while under anesthesia injected into the spine.

Who can participate?
Older patients having surgery on their legs or hips with anesthesia injected into the spine at the Chinese People's Liberation Army General Hospital

What does the study involve?
Patients will be divided into two groups: the control group (with 60 patients) and the music group (also with 60 patients), using a random number table. Patients in the music group will wear headphones and listen to relaxing music via an MP3 player during the surgery. Patients in the control group will wear the same headphones but will not listen to music during the procedure.

What are the possible benefits and risks of participating?
The benefits of taking part are: (1) Getting access to new treatment options. (2) Lessening the financial strain. (3) Learning more about the most recent information concerning your illness. (4) Receiving additional attention from doctors. (5) Reaching high-quality medical care.
The risks of taking part are: Needing to use more energy and the chance that the treatment may not work.

Where is the study run from?
Department of Orthopedics, PLA General Hospital of China

When is the study starting and how long is it expected to run for?
February 2022 to October 2023

Who is funding the study?
Department of Orthopedics, PLA General Hospital of China

Who is the main contact?
Xuanxuan Zhang, gzgk2021@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
20220201

Study information

Scientific Title
Analysis of therapeutic effect of music therapy on patients with lower extremity orthopedic operation under intravertebral anesthesia

Study objectives
Music therapy can reduce anxiety and improve satisfaction in patients undergoing lower extremity orthopedic surgery under intravertebral anesthesia

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/02/2024, Ethics Committee of the Chinese People's Liberation Army Southern Theater Command General Hospital (Southern War Zone General Hospital, No. 110, Liuhua Road, Yuexiu District, GuangZhou, 510010, China; +86 20-88686180; gzgcp2012@163.com), ref: None

Primary study design
Interventional

Study design
Interventional randomized parallel trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Patients undergoing lower extremity orthopaedic surgery under intravertebral anesthesia

Interventions
A total of 120 elderly patients will undergo lower extremity orthopaedic surgery under vertebral anaesthesia in the General Hospital of the Chinese People's Liberation Army. Patients will be divided into a control group (n=60) and a music group (n=60) according to a random number table. Patients in the music group will wear headphones and use MP3 to play relaxing music during the operation. Patients in the control group wore the same headphones but did not play music during the procedure.

Intervention Type
Mixed

Primary outcome(s)
1. Levels of perioperative anxiety measured using The Visual Analog Scale for Anxiety (VAS-A), at pre-operation and post-operation.
2. Hemodynamic Parameters: Heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) measured using continuous monitoring during surgery to provide real-time information on autonomic response using standard medical monitoring equipment, at entry into the operating room (baseline T1), 5 minutes after entering the operating room (T2), before induction of anesthesia (T3), 5 minutes after anesthesia (T4), at the beginning of the operation (T5), 5 minutes after the operation (T6), 30 minutes (T7), 60 minutes of surgery (T8), end of surgery (T9), and one hour after surgery (T10).
3. Salivary Cortisol Levels which is an indicator of stress. Measured using saliva samples collected by the patients themselves using test tubes containing 0.2% trifluoroacetic acid (TFA), followed by centrifugation and measurement using an ELISA (AB154996 Cortisol ELISA kit, Abcam, Cambridge, UK) according to the kit instructions at 15 minutes after waking up on the day of surgery (pre-operation) and the next day (post-operation).
4. Patient Postoperative Satisfaction measured using a standardized homemade questionnaire that includes a question about the satisfaction of the surgery procedure with five answers: A. very satisfied; B. Satisfaction; C. undecided; D. Dissatisfied; E. Very dissatisfied at Post-operation

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Age ≥ 60 years
2. Undergoing lower limbs orthopedic surgery under intravertebral anesthesia
3. Volunteer to participate in this study and sign the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 Years

Upper age limit
83 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Patients with a history of mental illness, hearing impairment, or contraindications to listening to music;
2. Passive position, completely unable to swing anaesthesia position;
3. Coagulation disorders, bleeding tendency and patients taking anticoagulant drugs
4. Patients with shock, circulatory function is unstable
5. Patients with infection of the skin at the puncture site of the corresponding segment
6. Patients with injuries of the spinal column, which cause changes in the position or patients with a history of trauma to the spinal column

Date of first enrolment
01/02/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
China

Study participating centre

Department of Orthopedics, PLA General Hospital
The General Hospital of the People's Liberation Army of the Southern Theater, No. 111, Liuhua Road, Yuexiu District
Guangzhou
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510010

Sponsor information

Organisation
PLA General Hospital, Southern Theater Command

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Orthopedics, PLA General Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/09/2024	30/06/2025	Yes	No