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Effects of music on pre- and intraoperative anxiety through assessment of pupil size and vital signs (blood pressure, respiratory and pulse rates) among cataract surgery patients in the University of Nigeria Teaching Hospital in Enugu

Submission date
12/11/2023

Recruitment status
No longer recruiting

Registration date
13/11/2023

Overall study status
Completed

Last Edited
14/11/2023

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Anxiety is a major problem in most surgeries done in ophthalmology and leads to various forms of complications. This study aims to determine the effect of music in reducing preoperative and postoperative anxiety in patients scheduled for cataract surgery with a view to recommending it as a non-pharmacologic way of reducing anxiety in elderly patients during cataract surgery.

Who can participate?
Patients aged 50 years old and above with uncomplicated cataract surgery

What does the study involve?
This research will take place at the University of Nigeria Teaching Hospital (UNTH) Department of Ophthalmology, located 21km from Enugu Metropolis. The department specializes in various eye-related fields.

Patients will be divided into two groups using a systematic random sampling method: Group A, who undergo surgery with music, and Group B, who undergo surgery without music. The study focuses on individuals aged 50 and above undergoing small incision cataract surgery with peribulbar anesthesia.

The goal is to investigate the impact of music on preoperative and intraoperative anxiety by measuring physiological indicators like pupil size, blood pressure, pulse rate, and respiratory rate.

What are the possible benefits and risks of participating?
Participation in this study will provide results that will help in bridging the knowledge gap on the

effects of anxiety during eye surgery. Additionally, this study will help to mitigate the comorbidities associated with surgical anxiety such as pain, expulsive choroidal haemorrhage from raised systemic blood pressure and corneal desiccation from dry eyes during surgery. There are no additional risks involved for the patients.

Where is the study run from?
University of Nigeria Teaching Hospital

When is the study starting and how long is it expected to run for?
November 2019 to November 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Chukwubuike Ezepue, unth.ophthalmology@gmail.com (Nigeria)

Contact information

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Public, Scientific, Principal investigator

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Study information

Scientific Title
This is a randomised Observational study, studying the Effects of music on pre- and intra-operative anxiety through assessment of pupil size and vital signs (Blood pressure, Respiratory and Pulse rates) among cataract surgery patients in UNTH-ENUGU, in which 98 patients underwent cataract surgery under regional anaesthesia - with and without music. Music was found to have an effect on pre-operative and intra-operative anxiety by positively affecting blood pressure, pulse rate, respiratory rate and pupil diameter (P<0.001)

Acronym
EOMOA

Study objectives
Does music have an effect on preoperative and intraoperative anxiety during cataract surgery?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/04/2020, University of Nigeria Health Research Ethics Committee (UNTH Ituku Ozalla, Enugu, 40001, Nigeria; +2348033458010; cmdunth2011@yahoo.com), ref: NHREC/05/01/2008B-FWA00002458-1RB00002323

Study design
Randomized observational study

Primary study design

Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Cataract

Interventions
This is a randomized observational study of individuals aged 50 years old and above who are scheduled for and undergoing cataract surgery, with music and regional anesthesia, matched with individuals 50 years and above scheduled for and undergoing cataract surgery without music but also with regional anesthesia in the Department of Ophthalmology operating theatre, UNTH, Ituku Ozalla Enugu.

It will be routine for all test and control groups. In Group A, the study participants will be informed about the study's components and objectives, and written informed consent will be obtained upon recruitment in the clinic. The patient will be admitted a day before the surgery and, after about 30 minutes of rest on the bed, baseline parameters, including blood pressure, pulse, respiratory rate, and pupil diameter, serve as an objective parameter for indirect assessment of anxiety. A blood pressure measurement will be performed, and the pupil diameter will be checked in the contralateral eye to avoid interference with the eye to be operated on.

Subjects are allowed to choose their preferred music before being transferred to the preoperative room. In the preoperative room, objective indices will be checked again in the same manner. The patient is given an earphone and helped place them in place. The preferred music will be turned on, and the volume will be adjusted to the patient’s satisfaction. After 5 min of listening to the music, the parameters will be measured again, after which peribulbar anaesthesia is administered. The subject is wheeled into the theatre with the instrument used to measure blood pressure and pulse still attached to the patient and the earphones still in situ with the music still playing. The surgeon will be blinded to the group of subjects, and the music played for the entire duration of the surgery. At the end of surgery, as soon as the drapes are removed, pupil diameter is measured in the contralateral eye. The music is then stopped and the patient is wheeled out of the theatre.

In Group B, the patients in this group will be processed the same way and in the same order as the patients in Group A for the baseline, preoperative and intraoperative stages. However, music will not be played though the earphones will be attached, as with the patients in Group A.

The participants would be randomized into two different study groups using a systematic sampling method. The first participant to be enrolled becomes a member of Group A (odd numbers) and the next participant to be enrolled becomes a member of Group B (even numbers). Placement into these two groups continues in the same manner alternately as they are enrolled. At the end of each day, the last group of participants to be enrolled will noted and the next day the other group of participants will start the day’s enrollment. For example, if five participants were enrolled in a day, with the fifth participant falling into the Group A category, the next day would start with the Group B participants being enrolled first. Odd numbers (Group A) will be for individuals who will undergo surgery while listening to music and even numbers (Group B) will be for individuals who will undergo surgery without music.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety will be measured using the Hamilton State-Trait Anxiety questionnaire at baseline, immediately on arrival in the preoperative room and 5 minutes after the intervention

Key secondary outcome(s))
The effect of music on anxiety measured using an assessment of pupil diameter (with a better rule), blood pressure, pulse rate (with a digital sphygmomanometer) and respiratory rate (with a digital stopwatch) at baseline upon admission, immediately on entrance into the pre-operative room, 5 mins after the intervention with music or without music then immediately after the surgery in the intra-operative room.

Completion date
20/11/2020

Eligibility

Key inclusion criteria
1. Age equal to or greater than 50 years
2. Scheduled for cataract surgery UNTH Ituku Ozalla.
3. Surgery must be with peribulbar regional anesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
130 years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Preadmission blood pressure greater than or equal to 150/100mmHg. Blood pressure will be taken with the patient lying down, sitting and standing to rule out a positional change in blood pressure.
2. Uncorrected hearing problems. Rinne’s and Weber’s tests will be done to ascertain this

diagnosis
3. Patients with a history of epilepsy
4. Diagnosed with dry eyes
5. Known to have any disorder affecting the size of the pupil such as trauma, Horner's syndrome, etc.
6. Cataracts younger than 50 years old
7. Major ocular comorbidity
8. Surgery in the non-index eye

Date of first enrolment
20/04/2020

Date of final enrolment
20/10/2020

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Nigeria Teaching Hospital
Ituku Ozalla
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Sponsor information

Organisation
University of Nigeria Teaching Hospital

ROR
https://ror.org/05fx5mz56

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data sets generated during and /or analysed during the current study will be available upon request from Chukwubuike Ezepue, Principal researcher, chibike_ezepue@hotmail.com. The type of data shared is an Excel result sheet, within 1 week of the request.
Consent was required and obtained. Data was collected for research purposes only and is stored in password-protected computers. The participants were also told that their data would not be accessible to a 3rd party without their consent and the research assistants were trained on the importance of data security regarding information and data collection. Interviews and screening were carried out privately, also the names of the participants will not be written on any of the questionnaires.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/11/2023	No	Yes