

# 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

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<b>Registration date</b> 13/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/11/2023	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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.ophtalmology@gmail.com (Nigeria)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## 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

### **Secondary study design**

randomised observational study

### **Study setting(s)**

Hospital

### **Study type(s)**

Efficacy

### **Participant information sheet**

### **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 be 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 measure**

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

### **Secondary outcome measures**

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.

### **Overall study start date**

15/11/2019

### **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

### **Age group**

Mixed

**Lower age limit**

50 Years

**Upper age limit**

130 Years

**Sex**

Both

**Target number of participants**

140

**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

Enugu

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40001

# Sponsor information

## Organisation

University of Nigeria Teaching Hospital

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<http://www.unthportal.org/>

## ROR

<https://ror.org/05fx5mz56>

# 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 review journal

## Intention to publish date

13/01/2024

## 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](mailto: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

[Participant information sheet](#)

Details

Date created

Date added

13/11/2023

Peer reviewed?

No

Patient-facing?

Yes