ISRCTN12556414 https://doi.org/10.1186/ISRCTN12556414

# Improved recovery following cardiac surgery through audio-visual experience

**Submission date**
27/03/2026

**Recruitment status**
Recruiting

**Registration date**
30/03/2026

**Overall study status**
Ongoing

**Last Edited**
08/05/2026

**Condition category**
Circulatory System

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

## Plain English summary of protocol

Background and study aims
After cardiac (heart) surgery, the body reacts to the stress of the operation, which can increase inflammation and make pain feel worse. This study aims to find out whether a relaxing audio-visual experience (combining calming sounds and images) can help improve recovery after heart valve surgery by reducing pain and stress.

Who can participate?
Adults scheduled to undergo planned (elective) aortic valve replacement or aortic valve repair surgery.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive a relaxing audio-visual experience designed to promote calmness, while the other group will receive standard care without this intervention. Researchers will compare the two groups by measuring pain levels, stress levels, and biological markers of stress, relaxation, and inflammation using saliva and blood samples. Participation will last up to six days after surgery.

What are the possible benefits and risks of participating?
Participants in the intervention group may experience reduced pain and stress, although this cannot be guaranteed. There are no significant risks expected beyond standard care, as the intervention involves non-invasive audio-visual relaxation. Some participants may find the experience unfamiliar or not helpful.

Where is the study run from?
Geneva University Hospitals (HUG), Switzerland.

When is the study starting and how long is it expected to run for?
The study is expected to begin in May 2026 and will run for approximately one year.

Who is funding the study?
The study is funded by the Schmieder-Bohrisch Foundation and the Cardiovascular Surgery Division of the Surgery Department at HUG, Switzerland.

Who is the main contact?
Prof Professor Christoph Huber, Head of Cardiovascular Surgery Division, Department of Surgery at HUG (Sponsor-Investigator), christoph.huber@hug.ch.

# Contact information


### Type(s)
Principal investigator

### Contact name
Prof Christoph Huber

### ORCID ID
https://orcid.org/0000-0001-9048-849X

### Contact details
Cardiovascular Surgery Division
Geneva University Hospitals (HUG)
Rue Gabrielle-Perret Gentile 4
Geneva
Switzerland
1205
+41 22 372 76 25
christoph.huber@hug.ch

### Type(s)
Scientific

### Contact name
Dr Elena Tessitore

### ORCID ID
https://orcid.org/0000-0003-1680-0152

### Contact details
Service de cardiologie
Hôpitaux Universitaires de Genève
Rue Gabrielle Perret Gentil 4
Geneva
Switzerland
1205
+4179 553 2615
elena.tessitore@hug.ch

### Type(s)
Public

### Contact name
Dr Daniela Dumitriu laGrange

### ORCID ID
https://orcid.org/0000-0002-2914-066X

### Contact details
Cardiovascular Surgery Division
Geneva University Hospitals (HUG)
Rue Gabrielle-Perret Gentile 4
Geneva
Switzerland
1205
+41 79 553 9870
daniela.dumitriulagrange@hug.ch

# Additional identifiers

# Study information

### Scientific Title
A patient-centered approach to improve recovery following cardiac surgery through audio-visual experience – a proof-of-concept randomized controlled trial

### Study objectives
The overarching hypothesis is that by using state-of-the-art technology to deliver positive, calming audio-visual stimuli in the context of perioperative care, the study will provide an environment conducive to enhanced patient recovery. Unlike other studies, in which the access to relaxation, as an intervention, was administered on a “prescription” basis, with pre-specified duration or sound frequency, this study posits that the "one size fits all" approach is an inefficient method of assisting patients in achieving a state of calm and comfort. In this study, patients are permitted and encouraged to select the type of audio-visual support, its timing, and its duration, according to their needs, for a maximal psychological and physiological effect. The objective of this proof-of-concept study is to evaluate the changes in postoperative pain levels associated with this intervention. In addition, the study aims to evaluate changes in physiological endpoints and in self-evaluated stress levels. This proof-of-concept study will also provide us information about the feasibility of testing this intervention in larger RCT, powered for investigating other important outcomes following cardiac surgery.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Submitted 28/01/2026, Swissethics Cantonal Research Ethics Commission (Swissethics Commission cantonale d'éthique de la recherche; CCER) (Rue Adrien-Lachenal 8, Geneva, 1207, Switzerland; +41 22 546 51 01; ccer@etat.ge.ch), ref: 2026-00172

### Primary study design
Interventional

### Allocation
Randomized controlled trial

## Masking
Open (masking not used)

## Control
Dose comparison

## Assignment
Parallel

## Purpose
Basic science, Supportive care

## Study type(s)

## Health condition(s) or problem(s) studied
Recovery following adult patients undergoing elective cardiac surgery for aortic valve repair or aortic valve replacement

## Interventions
Randomization will be performed using a computer program: a list for stratified block randomization will be generated in R and uploaded to REDCap.
Intervention: Allowing the patient to self-adjust to a state of psychological comfort and calm, through unrestricted access to a set of relaxing audio- or audio-visual stimuli, from the day before surgery and until postoperative day 5, as long as this is not impeding the delivery of standard of care:
- The utilization of noise-cancelling headphones to facilitate the absorption of nature derived sounds and calming music. A curated selection of several nature sounds, including forest and bird sounds, ocean waves, and river sounds, along with peaceful, relaxing music will be made available to each participant.
- Immersive three-dimensional virtual reality experiences featuring natural environments including forests, high mountains, and ocean beaches, are available. These sessions have a duration of 20 minutes, with a one-hour washout period recommended by the manufacturer between each session. Patients have the option to listen to a virtual voice (feminine or masculine) that guides their respiratory motion and relaxation, as this feature is available on HypnoVR devices. The HypnoVR device is CE marked as a Class 1 Medical Device, for use as a non-drug digital therapy in various medical fields like surgery and dentistry, ISO 13485 certified for quality management systems.

## Intervention Type
Behavioural

## Primary outcome(s)
1. Pain at rest measured using a Visual Analog Scale (VAS) at baseline, 48 and 96 hours after surgery

## Key secondary outcome(s)
1. Pain at movement measured using a Visual Analog Scale (VAS) at baseline, 48 and 96 hours after surgery

2. Stress self-evaluated measured using a Visual Analog Scale (VAS) at baseline, 48 and 96 hours after surgery

3. Salivary alpha-amylase (sAA) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (A2506, Antibodies.com) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

4. Salivary cortisol levels (nmol/l) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (EELR004, Thermo Fisher Scientific/Invitrogen) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

5. Salivary oxytocin levels (pg/ml) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (ADI-900-153A, Enzo) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

6. Plasma vasoactive intestinal polypeptide (VIP) (pg/ml) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (EEL186, Thermo Fisher Scientific /Invitrogen) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

7. Plasma interleukine-6 (IL-6) (pg/ml) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (88-7066-22, Thermo Fisher Scientific/Invitrogen) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

8. Plasma tumor necrosis factor alpha (TNF alpha) (pg/ml) measured using a commercially available enzyme-linked immunosorbent assay (ELISA) kit (88-7346-88, Thermo Fisher Scientific /Invitrogen) according to the manufacturer's instructions at baseline, 2 and 4 days after surgery

### Completion date
31/08/2027

## Eligibility

### Key inclusion criteria
1. Adult patients
2. Undergoing elective cardiac surgery for aortic valve repair or aortic valve replacement
3. Signed the informed consent form for participating in the study

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
All

### Total final enrolment

0

### Key exclusion criteria
1. Failure or inability to provide consent for participation in the study
2. Pregnant
3. Under the age of 18
4. Contraindications to headphones (eg. Cochlear implants, active infection)
5. History of psychotic symptoms or severe mental illness (e.g., schizophrenia, bipolar disorder)
6. History of seizures or uncontrolled epilepsy
7. Motion sickness or vestibular disorders
8. Significant visual or auditory impairment that would interfere with the experience
9. Claustrophobia
10. Chronic gastrointestinal disease
11. Metabolic disorders: diabetes, autoimmune thyroid disease (graves'), vipomas
12. Autoimmune disorders: multiple sclerosis, inflammatory bowel disease, rheumatoid arthritis, spondyloarthritis

### Date of first enrolment
15/08/2026

### Date of final enrolment
31/05/2027

## Locations

### Countries of recruitment
Switzerland

## Sponsor information

### Organisation
University Hospital of Geneva

### ROR
https://ror.org/01m1pv723

## Funder(s)

### Funder type

### Funder Name
Hôpitaux Universitaires de Genève

### Alternative Name(s)
Geneva University Hospitals, HUG

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
Switzerland

**Funder Name**
Schmieder-Bohrisch Foundation

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available