

# Efficacy of a Web App–Based Music Intervention During Cataract Surgery A Randomized Clinical Trial

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**IMPORTANCE** Hypertensive events during cataract surgery may induce complications. Information and communication technologies applied to health are popular, but clinical evidence of its usefulness is rare and limited to treating anxiety without specific analysis. Recent publications have described the potential effects of personalized music choices as mobile-based intervention on pain but not on anxiety.

**OBJECTIVE** To demonstrate the effects of a web app–based music intervention on the incidence of hypertension in participants during cataract surgery performed under local anesthesia.

**DESIGN, SETTING, AND PARTICIPANTS** This randomized, single masked, controlled clinical trial was composed of 2 arms and took place at a single center at Cochin Hospital in Paris, France. A total of 313 participants were screened between February 2017 and July 2018. Among these, 311 participants undergoing a phacoemulsification procedure for elective surgery for their first eye cataract under local anesthesia were enrolled. Analysis was intention to treat and began in September 2018 and ended November 2018.

**INTERVENTIONS** Participants requiring cataract surgery were assigned randomly to either the experimental arm (web app–based music listening intervention delivered via headphones) or control arm (noise-cancelling headphones without music) for 20 minutes before surgery.

**MAIN OUTCOMES AND MEASURES** The occurrence of at least 1 hypertensive event during surgery.

**RESULTS** A total of 310 participants were randomized in the study (155 to each arm) and 309 were analyzed (1 participant in the music arm had already undergone cataract surgery to the other eye). The mean (SD) age of the participants was 68.9 (10.8) years, and there were 176 female individuals (57%). On the primary end point, the incidence of hypertension was significantly lower in the music arm (21 [13.6%]) than in the control arm (82 [52.9%]), with a difference between the 2 arms of 39.3% (95% CI, 21.4%-48.9%;  $P < .001$ ). Regarding the secondary end points, the mean (SD) visual measure of anxiety was lower in the music arm (1.4 [2.0]) than in the control arm (3.1 [2.4]), with a difference of 1.5 (95% CI, 1.0-2.1;  $P = .005$ ). The mean (SD) number of sedative drug injections required during surgery was 0.04 (0.24) vs 0.54 (0.74) in the music vs control arms, respectively, with a difference of 0.50 (95% CI, 0.43-0.57;  $P < .001$ ).

**CONCLUSIONS AND RELEVANCE** For participants similar to those enrolled in this study, the trial suggests that a web app–based personalized music intervention before cataract surgery may be considered to lower anxiety levels and hypertension or reduce the need for sedative medication.

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Cataract surgery is the most frequently performed operation in high-resource countries.<sup>1</sup> In most cases, the phacoemulsification procedure is performed under local anesthesia in an outpatient unit. Overall, up to 80% of patients experience anxiety before surgery,<sup>2</sup> including cataract surgery.<sup>3</sup> Anxiety causes stress that in turn drives the cardiovascular system to respond by activating the sympathetic nervous system,<sup>4</sup> resulting in elevated heart rate and blood pressure (BP) levels. These mechanisms can complicate the surgical procedure owing to increased intraocular pressure.<sup>5</sup> Hypertension and tachycardia above 85 beats per minute represent an increased risk of orbital hemorrhage during the injection of a local anesthetic and of potential perioperative suprachoroidal expulsive hemorrhage.<sup>6</sup> Therefore, special arrangements are suggested for patients with severe anxiety.

The provision of information on the safety of cataract surgery<sup>7</sup> and the informed consent process<sup>8</sup> can contribute to reducing patient anxiety. However, high-quality individual preoperative patient counseling remains challenging in view of the busy clinical environment. In addition, some patients prefer distraction to ease anxiety rather than information on the procedure.<sup>9</sup> One effective nonpharmacologic approach to anxiety before surgery is music intervention. Music augments positive reward pathways in the brain and functions to reinforce a healthy engagement with disease states.<sup>10</sup>

Music interventions in perioperative and postoperative settings in general surgery can have positive effects on reducing patient anxiety.<sup>11,12</sup> Paying attention to personal musical preferences and cultural background is considered to be one of the main characteristics of a successful musical intervention.<sup>13</sup> According to the literature, music sessions should last between 20 and 60 minutes (at approximately 60 to 80 beats per minute), be instrumental (nonlyrical), and consist principally of harmonic variations.<sup>14</sup> Finally, although it is often nurses who administer the recorded music, a consultation with, or supervision by, a trained music therapist who can tailor music to individual preferences is strongly encouraged.<sup>15</sup>

Based on these recent scientific recommendations, a web app–based personalized music intervention has been developed: the U sequence based on a musical composition algorithm. The music sequence can last from 20 to 60 minutes and is divided into several phases that gradually enable the patient to lower pain and anxiety levels in line with the U sequence technique.<sup>16–18</sup>

Recent technological developments now enable patients and/or caregivers to control the use of music-based interventions at the bedside using handheld devices. Previous studies had confirmed the effectiveness of this web app–based music intervention in reducing pain and/or anxiety in patients with a variety of conditions.<sup>19</sup> However, little is known about nonpharmacologic approaches to anxiety during cataract surgery performed while the patient is awake. They could offer an inexpensive method to reduce anxiety in these patients. Furthermore, music may theoretically reduce anxiety in the surgeon and even improve surgical performance, although this has not been adequately studied to date. Therefore, the principal objective of this study was to describe the effects of a web app–based music intervention on the incidence of hyperten-

## Key Points

**Question** What are the effects of a web app–based music intervention on anxiety and hypertensive events during cataract surgery?

**Findings** In this randomized clinical trial of 309 adults, the proportion of hypertensive events was 14% in the group receiving music intervention vs 53% in the group without a music intervention.

**Meaning** Before cataract surgery, use of a web app–based music intervention may be of interest because this trial showed it could reduce a participant’s anxiety levels and hypertension.

sion in patients during cataract surgery performed under local anesthesia.

## Methods

### Study Design

This was a randomized, single-masked, controlled clinical trial with 2 arms (music and control). The surgical team (surgeon, anesthesiologist, operating room nurses) members were all masked from the intervention. Only the participant and recovery room nurse were not masked. The study was reviewed and approved by the relevant regional Ethics Committee from the Regional Health Agency at Paris-Ile-de-France III. This randomized clinical trial was performed in accordance with Consolidated Standards of Reporting Trials (CONSORT) reporting guideline. The trial protocol is available in English and French in [Supplement 1](#).

### Participants

Written informed consent was obtained from all the participants. Exclusion criteria included participants with severe hearing loss or speech impairment, those experiencing uncontrolled hypertension or psychiatric disorders, those deprived of liberty by a judicial or administrative decision, those under trusteeship or guardianship, or those experiencing dementia. Uncontrolled hypertension was defined as systolic BP level more than 140 mm Hg and/or diastolic BP level more than 90 mm Hg during the preanesthesia consultation despite the use of antihypertensive medication. Race and ethnic groups were not reported because this is not usual practice in France. Eligible participants were electively undergoing their first eye cataract surgery under local anesthesia at Cochin Hospital in Paris, France. Participants were enrolled between February 2017 and July 2018. Unilateral cataract surgery only was performed. No incentives or compensations were offered to patients to participate to the study. The patient flowchart is presented in [Figure 1](#).

Participants’ ocular and medical history, including systemic hypertension, cardiovascular disease, diabetic status, and usual medications, were recorded. On the day of the cataract surgical procedure, participants were allocated at random to a music arm (headphones with music) or a control arm (headphones with no music) using a computer-generated, interac-

Figure 1. Flow Diagram of Patients

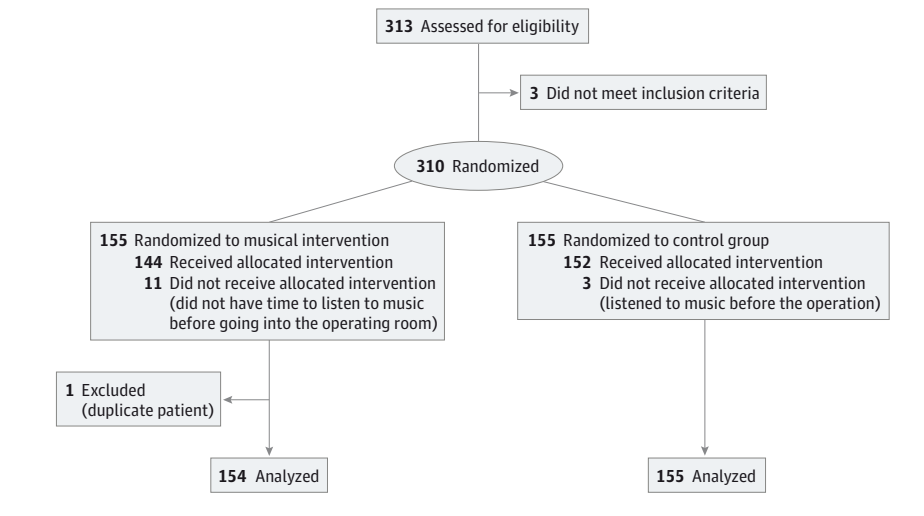
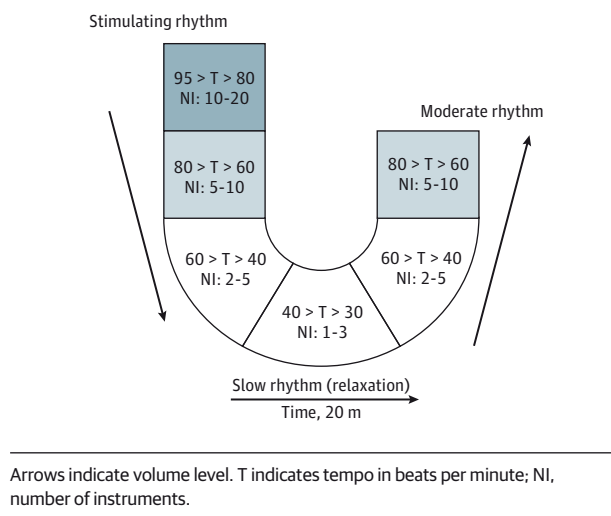


Figure 2. U Sequence



tive web-response system (CleanWEB, Telemedicine Technologies).

### Music Intervention

Participants in the music arm were shown how to handle the tablet interface (Samsung Galaxy; Samsung) by a nurse or nursing assistant trained in using the Music Care web app with the U sequence technique (Figure 2) that is designed to gradually relax the listener.<sup>19</sup> Participants were asked to choose their musical program according to their preferences, set the volume level on the headphones, and start a 20-minute session.

In the control arm, the same insulating headphones (Bose AE2; Bose) were placed on the participants' ears but without any music. In both arms, the headphones and sleeping mask placed over the eyes were left in place for 20 minutes. The participants were aware of the 2 interventions (music vs no music).

The musical intervention was stopped just before the surgical procedure to improve communication between the surgeon and participant, a decision taken in light of the proven long-lasting effects of music on anxiety described in the literature. All participants were advised to take their usual medications on the day of the cataract surgical procedure. Whether participants with hypertension had or had not taken their BP medications was recorded.

### End Points

The primary end point was the occurrence of at least 1 hypertensive event during cataract surgery, defined in the protocol as systolic BP level more than 160 mm Hg and/or diastolic BP level more than 100 mm Hg combined with tachycardia level more than 85 bpm. Secondary end points concerned the evolution of anxiety at the end of the music intervention, the mean quantities of anxiolytic drugs injected during the surgical procedure, and the duration of the surgical procedure. Anxiety levels determined using a visual analog scale (VAS rated from 0 to 10), BP level, and heart rate were all recorded before and after the music intervention, preoperatively, and postoperatively in the recovery room. It had previously been shown that using a VAS is a reliable indicator of preoperative anxiety.<sup>20</sup>

### Cataract Surgery

Oral midazolam, 0.03 mg/kg, was administered before the cataract surgical procedure to participants assessed as experiencing anxiety (VAS, >0). Topical anesthesia consisted in the administration of oxybuprocaine, 0.5%, drops into the conjunctival sac 3 times during the 15 minutes preceding the cataract surgical procedure. After aseptic preparation, a speculum was inserted to hold the eyelids open and the illumination of the operating microscope was gradually increased to the minimum intensity necessary for cataract surgery. Cataract extraction was performed after endocapsular phacoemulsification, followed by implantation of a hydrophobic acrylic intraocular lens. An intracameral injection of 1 mg of cefurox-

ime was administered at the end of cataract surgery. BP levels were monitored every 2 minutes while heart rate was monitored continuously. The highest BP and heart rate values were then recorded. The injection of sedatives (midazolam) or hypotensive drugs (nicardipine) was left at the discretion of the anesthetist. Any perioperative or intraoperative complications were recorded. The primary outcome was assessed under masked conditions by a nurse or nursing assistant from the operating room, after having removed and stored all equipment and before the participant left the recovery room.

### Statistical Analysis

Assuming a 20% frequency of onset of at least 1 perioperative hypertensive event and anticipating that the use of music would reduce this frequency by 50%, a sample size of 155 participants per arm was deemed necessary to detect this expected difference at the .05 level of significance and 80% power. Once randomized, participants were included in an intent-to-treat analysis to provide unbiased comparisons between the treatment arms. In the event of missing data on the primary end point, participants were treated as a treatment failure, meaning they were considered as having experienced a perioperative hypertensive event. Continuous data were presented as means and SDs, while categorical data were represented by numbers and percentages. Unless otherwise specified, categorical variables were compared using a  $\chi^2$  test or Fisher exact test as appropriate and continuous variables were compared by means of *t* test or a Wilcoxon-Mann-Whitney test, as appropriate. No adjustments for covariates were done because the 2 arms did not appear to be imbalanced. All calculations were performed using SAS statistical software version 9.4 (SAS Institute). All *P* values were 2-tailed and considered to be significant at the .05 level for the primary outcome. There were no adjustments for multiple analyses, and no interim analyses were performed. Analysis began September 2018 and ended November 2018.

## Results

A total of 311 participants undergoing a phacoemulsification procedure were enrolled in this prospective, randomized, and controlled clinical study. Five surgeons participated in the study and operated on equal numbers of participants. Among these 311 participants, 310 were randomized (155 to the music arm and 155 to the control arm; Figure 1); 1 participant in the music arm had already undergone cataract surgery on the other eye and was therefore excluded from the intent-to-treat analysis. The results of this randomized clinical trial are presented in compliance with the guidelines from the Consortium on the Assessment of Non-pharmacological Treatments.<sup>21,22</sup>

The sociodemographic characteristics and medical history of participants are described in Table 1. The mean (SD) age of the participants was 68.9 (10.8) years. There were 176 female individuals (57%). In all, 36 participants (12%) were receiving treatment for hypertension. All but 2 participants (1 in each arm) had taken hypertensive medications before the procedure. Five participants (1.6%) had the sight of 1 eye, while

Table 1. Baseline Characteristics

Characteristic	No. (%)	
	Music intervention arm (n = 154)	Control arm (n = 155)
Age, mean (SD), y	68.5 (11.2)	69.2 (10.8)
Sex		
Female	83 (54)	93 (60)
Male	71 (46)	62 (40)
Patients with sight of 1 eye	2 (1)	3 (2)
Treated hypertension	38 (25)	37 (23)

17 (5.5%) had already undergone ophthalmic cataract surgery under local anesthesia. The proportion of participants receiving premedication was similar in both arms (95 [62%] and 107 [69%] in the music and control arms, respectively). No differences were observed regarding waiting times between admission, musical intervention, and surgical procedure. The duration of the sound intervention (20 minutes) was achieved in all but 13 of the participants included (12 in the music arm and 1 in the control arm) where the session was stopped early so as not to disturb the surgical workflow.

Before the intervention, mean (SD) VAS anxiety levels were similar in both arms: 3.3 (2.5) in the music arm and 3.5 (2.5) in the control arm. In the music arm, the difference in anxiety levels before and after the intervention was 1.9 (95% CI, 1.1-4.8), while in the control arm it was 0.4 (95% CI, 0.1-1.7). A more marked reduction (*P* = .003) in anxiety levels before and after the intervention was thus observed in the music arm, the difference between the arms being 1.6 (95% CI, 0.2-2.3). The mean (SD) BP level recorded was 137/69 (15/13) mm Hg in the music arm and 140/69 (18/11) mm Hg in the control arm, while the mean (SD) heart rate recorded was 77 (10) bpm in the music arm and 78 (12) bpm in the control arm. After the intervention, the mean (SD) heart rate was 69 (7) bpm and 71 (13) bpm in the music and control arms, respectively. Mean (SD) BP levels recorded after the intervention were 130/69 (14/11) mm Hg in the music arm and 138/75 (23/13) mm Hg in the control arm (Table 2). There was no difference between the reduction of systolic and diastolic BP after the intervention in the music arm than in the control arm, with values of 2.8 (95% CI, 1.6-7.9) for systolic BP (*P* = .12) and 4.3 (95% CI, 2.1-10.8) for diastolic BP (*P* = .43). No differences in heart rate before and after the intervention were observed between the arms (reductions of 8 bpm in the music arm and 7 bpm in the control arm).

During cataract surgery, the incidence of hypertensive events was significantly lower in the music arm (21 [13.6%]) than in the control arm (82 [52.9%]), the difference being 39.3% (95% CI, 21.4%-48.9%; *P* < .001) (Table 3). Only 1 hypertensive event was seen among patients during surgery.

As for the secondary end points of the study, mean (SD) anxiety levels determined using the VAS just before surgery were 1.4 (2.0) and 3.1 (2.4) in the music and control arms, respectively (difference, 1.5 [95% CI, 1.0-2.1]; *P* = .005). The proportion of participants requiring control of anxiety during surgery was comparable in both arms: 101 participants (66%) and 95 participants (61%) needed midazolam in the intervention and control arms, respectively.

Table 2. Description of Preoperative Data

Measurement	Mean (SD)	
	Music intervention arm (n = 154)	Control arm (n = 155)
Blood pressure level, mm Hg		
Before music intervention		
Systolic	137 (15)	140 (18)
Diastolic	69 (13)	69 (11)
After music intervention		
Systolic	130 (14)	138 (23)
Diastolic	64 (11)	75 (13)
Heart rate, beats/min		
Before music intervention	77 (10)	78 (12)
After music intervention	69 (7)	71 (13)
Anxiety level		
Before music intervention	3.3 (2.5)	3.5 (2.5)
After music intervention	1.4 (2.0)	3.1 (2.4)

The mean (SD) number of midazolam injections required during surgery was 0.04 (0.24) in the music arm vs 0.54 (0.74) in the control arm (difference, 0.50 [95% CI, 0.43-0.57];  $P < .001$ ). One participant (0.6%) from the music arm and 6 participants (4%) in the control arm received hypotensive medication during cataract surgery.

The mean (SD) operating time tended to be shorter in the music arm (16.3 [7.1] minutes) than in the control arm (16.9 [5.8] minutes; difference, 0.60 [95% CI, 0.27-0.93];  $P = .07$ ). No surgical complications were observed. One case of vasovagal syncope was the only medical complication reported (Table 3).

## Discussion

This single-masked, prospective, randomized, controlled assessment of a web app–based music intervention before cataract surgery demonstrated a significant reduction in hypertensive events during phacoemulsification. An improvement in anxiety levels was also demonstrated.

To our knowledge, the benefits of music intervention in terms of easing perioperative anxiety in patients undergoing cataract surgery had only previously been assessed during 1 nonrandomized and unmasked study.<sup>23</sup> Our results suggest that this simple nonpharmacological intervention could be generalized to reduce anxiety in the preoperative setting. In view of the small difference in VAS anxiety scores between the arms of this study, its clinical significance may appear limited. However, further reports focused on patients with high anxiety may provide more convincing clinical benefits. In addition, a reduction in the number of drugs injected to reduce anxiety or hypertension during the procedure was reported. This could be of particular interest in outpatient settings in that it avoids adverse effects such as drowsiness and shortens the hospital stay. Interestingly, despite some music sessions being halted prematurely in a few participants, music still had beneficial effect in terms of reducing anxiety. This was in line with other findings where as little as 15 minutes of listening to self-

selected music procured a significant reduction in anxiety.<sup>24</sup> Unsurprisingly, we observed a relatively low level of baseline hypertension in our cohort because of the noninclusion of participants with uncontrolled hypertension.

BP and heart rate levels were lower during surgery in participants receiving the music intervention than in the control arm. Because the music session lasted only 20 minutes, a noticeable remnant relaxing and anxiolytic effect was observed. Similar long-lasting effects of relaxing music have been reported in other studies<sup>25</sup> showing that a reduction in BP is sustained after the end of the music session. Neuroscience findings have indicated that music is processed differently in the brain depending on an individual's musical background and skills.<sup>26,27</sup> The present study was able to demonstrate that a web app–based music intervention offers a simple and cost-effective method to deliver the U sequence algorithm as treatment for anxiety. It is now necessary to explore the effects of music intervention on preoperative anxiety by comparing patients who listen to researcher-selected or predetermined music vs patients who listen to no music at all.

## Limitations

We need to acknowledge several limitations to our study. First, the participant's state of anxiety and depression was not assessed using validated questionnaires before enrollment and this might have biased their self-reporting of anxiety. However, there were no differences in the use of psychotropic medications between the 2 arms. Second, surgeon satisfaction was not evaluated. The operator's views might have helped to produce a qualitative quantification of the effect of music on the procedure. Third, the choice of hemodynamic parameters as a proxy for anxiety could be questioned, as other factors may influence variations in BP levels and heart rate, including pain and discomfort. Because local anesthesia using topical oxybuprocaine, lidocaine gel, and intracameral lidocaine ensured efficient analgesia, we believe that all procedures were performed under pain-free conditions. Extremely low levels of pain are usually reported in this context.<sup>28,29</sup> We acknowledge that hemodynamic markers may lack specificity with respect to anxiety because there is no standard definition for anxiety-related hypertension. Our definition of anxiety-related hypertension was based on the hemodynamic changes observed during anxiety caused by the white coat effect<sup>30</sup> and before surgery.<sup>31</sup> Refined physiological markers of anxiety need to be identified and developed. It might also be useful to validate objective tools to assess anxiety, such as pupillometers and heart rate variation analyzers. Fourth, participants randomized to not listen to music may have been more stressed because they knew they were not receiving the music intervention. Fifth, participant satisfaction, which is a multidimensional experience, was not assessed and the music intervention may have a greater effect on other dimensions than that explored during this study. Finally, because this trial was designed to enable more than 1 study end point to conclude as to the establishment of efficacy, we should perhaps have planned for multiple adjustment methods.

European guidelines in anesthesia now recommend the systematic management of preoperative anxiety.<sup>32</sup> As well as



Table 3. Comparison of Intraoperative Data

Measurement	Music intervention arm (n = 154)	Control arm (n = 155)	Difference between groups (95% CI)	P value
Incidence of hypertension with tachycardia, No (%) (95% CI)	21 (13.6) (8.2-19.1)	82 (52.9) (45.1-60.8)	39.3 (21.4-48.9) NA	<.001 NA
Blood pressure level during hypertensive event, mean (SD), mm Hg				
Systolic	149 (25)	179 (28)	30 (12-43)	.001
Diastolic	95 (12)	118(13)	23 (5-29)	.002
Anxiety level after music intervention, mean (SD)	1.4 (2.0)	3.1 (2.4)	1.5 (1.0-2.1)	.005
Heart rate during hypertensive event, mean (SD), beats/min	94 (5)	119 (7)	25 (11-38)	<.001
Received hypotensive drugs during cataract surgery, No. (%)	1 (0.6)	6 (4)	3 (1-8)	NA
Perioperative complications, No (%)	0 (0)	1 (0.6)	NA	NA
Sedative drugs injected, mean (SD)	0.04 (0.24)	0.54 (0.74)	0.50 (0.43-0.57)	<.001
Duration of procedure, mean (SD), min	16.3 (7.1)	16.9 (5.8)	0.60 (0.27-0.93)	.07

Abbreviation: NA, not applicable.

other nonpharmacological tools such as patient information videos,<sup>33</sup> music might significantly lower perioperative anxiety levels. Further analysis is now necessary to assess the effect of this intervention on preoperative workflow, costs, and time before this approach is more widely included in patient assessment.

## Conclusions

This study offers empirical evidence that a patient-controlled music intervention, specifically using a web app-based music intervention, can improve the overall effect and

consequences of anxiety on cataract surgery. By reducing hypertension, levels of anxiety, and the need for sedative drugs during the procedure, a 20-minute music intervention before cataract surgery based on the U sequence algorithm appears to offer an effective treatment for anxiety, thus highlighting the importance of listening to music in decreasing its debilitating effects. Furthermore, this treatment is easily accessible and distributable via its computer- and smartphone-based application. Overall, we would like to stress the positive effects of using a web app-based music intervention as potential large-scale treatment for those who experience anxiety and possibly in the context of other types of surgical procedures.

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**Drafting of the manuscript:** Guerrier, Rothschild.

**Critical revision of the manuscript for important intellectual content:** All authors.

**Statistical analysis:** Guerrier, Abdoul, Jilet.

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**Additional Contributions:** The nurses and nursing assistants at the 3 study centers ensured the well-being of the participants. The Clinical Research Unit-Clinical Investigation Center, within hospital support structure dedicated to research that helps and support physicians in carrying out their clinical research projects, contributed in the implementation, monitoring and data management of the study.

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