

**STress Responses Amongst Undergraduates and Surgeons performing Simulated Surgical tasks: A cross-over study on the effect of background music during surgical tasks (STRAUSS)**

Study Protocol

21st of February 2023

Version 1

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# 1. ADMINISTRATIVE INFORMATION

## 1.1 Full/long study title

STress Responses Amongst Undergraduates and Surgeons performing Surgical tasks (STRAUSS): A cross-over study on the effect of background music during surgical tasks

## 1.2 Short study title

The STRAUSS Study

## 1.3 Research reference numbers

|  |  |
| --- | --- |
| HDEC Number: |  |
| UTN Number:  | U1111 1288-7255 |
| ANZCTR Number: | Request number: 385474 |

## 1.4 Key study contacts

|  |  |
| --- | --- |
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| Primary contact | Dr Anantha Narayanan(details as above) |
| Sponsor | The Royal Australasian College of Surgeons |
| Funder(s) | The Royal Australasian College of Surgeons |
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## 1.5 Study summary

|  |  |
| --- | --- |
| Study Design | Randomised Non-blinded Crossover Trial with allocation concealment and balanced allocation in a simulated environment – where background music is the intervention |
| Study Participants | Experienced and inexperienced operators |
| Planned Size of Sample  | 20 participants |
| Planned Study Period | March 2023 – December 2023 |
| Research Question/Aim(s) | While operating, do surgeons experience a physiological (autonomic) stress and psychological stress which is affected by the presence of background music? |
| Key MeSH Terms | Music, surgery, simulation, stress, autonomic nervous system |

## 1.6 Funding and support in kind

|  |
| --- |
| **FUNDER(S)**(Names and contact details of ALL organisations providing funding and/or support in kind for this study) |
| **Royal Australasian College of Surgeons (RACS) – Scholarships and Grants Committee** |
| **Specialty Trainees of New Zealand (STONZ)** |

# 2 INTRODUCTION

## 2.1 Background

Surgery can be a stressful exercise that warrants expert execution of both technical and non-technical skills (such as communication, teamwork and rapid decision-making) under pressure. The feeling of stress, and managing its flow-on effects to performance is one that unites all surgeons in their experience.1 Music can be one way in which surgeons can alter their operating environment, it is perhaps not surprising to find that it is played commonly in operating theatres (OT) throughout the world.2-4 Though, commonplace as it is, there is disagreement in the literature in regard to the perceptions of the benefits or harms that music can have in this context.

While it is clear that noise is deleterious to the surgical team5-10, many clinicians find music to be a generally favorable part of the theatre environment4 11 12, with music being seen as improving calmness2, stress13 14, mood, surgeon and overall team performance4. However, respondents’ opinions differed when it came to the distracting effect of music11 13, particularly at times of critical situations2-4 11 – factors which may affect performance, increase the feeling of difficulty, or stress.15 Communication is another contentious area, where several studies report no effect or a positive influence with music2 4 14 16, though others finding reduction in auditory speech perception10 17 and an increase in repeated request rate18.

Since, the seminal paper by Rauscher et al on the “Mozart effect” demonstrating an improvement with spatial reasoning skills after listening to Mozart, there has been interest in the interaction between music and task performance.19 Recent systematic reviews concluded that having background music may also improve surgical accuracy and speed20, and reduce mental workload in the simulated setting.21 It could be that the experience of stress may be a contributing or even fundamental factor bridging the gap between music and surgical performance.

In fields such as music therapy and occupational ergonomics, music is used to facilitate mood regulation,22 and to adjunct learning.23 A recent systematic review undertaken by the authors found while there is generally a positive perception towards intra-operative music and surgeon stress, there is little definitive high-quality objective physiological and psychological data to support this.24

For these reasons, CONSORT guidelines were followed to design a crossover randomized controlled trial regarding the effect of background music on a surgeon’s experience of stress while performing simulated surgical tasks.

## 2.2 Aims and objectives

### 2.2.1 Central Hypothesis

While operating, do surgeons experience a physiological (autonomic) stress and psychological stress which is affected by the presence of background music?

### 2.2.2 Primary Objective

Determine the influence of background music on physiological parameters (sympathetic nervous activity, peripheral and central chemoreflex responses, ventilatory responses, cerebral blood flow) and psychological parameters (taskload and anxiety scores) in surgeons (experienced and inexperienced) while performing simulated surgical tasks

### 2.2.3 Specific hypothesis 1

In the presence of background music, while performing high-focus tasks, surgeons will experience lower levels of psychological and physiological stress when compared to the control.

### 2.2.4 Specific hypothesis 2

The reduction in physiologic and psychologic stress response with music may be reduced in experienced operators when compared to inexperienced operators

## 2.3 Outcome measures

### 2.3.1 Primary Outcome

* Blood pressure and heart rate variability
* Surgical Taskload

### 2.3.2 Secondary Outcome

* Ventilatory responses (repiratory rate and volume, and end-tidal CO2)
* Cerebral Blood Flow
* Skin conductance
* Anxiety inventory scores
* Performance measures – time to completion, subjective self-assessment of work, objective assessment by blinded assessors.

## 2.4 Expected value of results

1. The use of music in the operating theatre remains controversial, with a wide ranging views on type, and its effect on the operating theatre environment, surgeons and teamwork.
2. Understanding elements of the theatre environment and how they impact on staff is useful when considering the workplace from an ergonomic perspective. An understanding of the concept of the optimal ergonomic operating environment may guide hospital and institutional policy when designing new or remodelling old operating spaces.
3. There is increasing awareness of clinician mental wellbeing, burnout and stress. Finding ways to prevent or mitigate the effects of stress in the workplace may provide ling term benefit to clinicians and the broader workforce.
4. While it would be challenging to correlate background music to surgical outcomes, there is a wide understanding that safe and quality surgical care arises due to a symphony of factors which include patient, surgeon, team, institution. A deeper understanding of the acoustic environment in theatre may contribute a small piece to a much larger puzzle.

# 3 STUDY DESIGN

## 3.1.1 Study setting

Data will be collected in the Human Physiology Laboratory, Department of Physiology, Faculty of Medicine and Health Sciences, University of Auckland

## 3.1.2 Study Design

This is a two-armed non-blinded randomised controlled crossover trial, using allocation concealment. One arm of the trial will be the music condition, and the control will be without music. Participants will be compared against themselves in each condition. Blinding is not possible, so block randomisation with allocation concealment will be utilised.

## 3.2 Participants

### 3.2.1 Inclusion criteria

* Qualified or training surgeons from any surgical sub-specialty
* Inexperienced operators (clinical medical students)
* Men and women;
* Aged over 18 years;

### 3.2.2 Exclusion criteria

* Significant physical impairment that inhibits completion of dextrous tasks
* Current pregnancy
* Significant arrhythmias (e.g., atrial fibrillation, previous VT / significant ventricular ectopy)
* Hemodynamically significant valvular heart disease (e.g., stenosis, mechanical valve replacement)
* Severe left ventricular systolic dysfunction
* Recent acute coronary syndrome (<12 months) (e.g., MI, angioplasty, unstable angina)
* Recent stroke/TIA (<12 months)
* Inability to fully or appropriately provide consent (e.g., language issue, reading capability)
* Underlying medical conditions, which in the opinion of the Investigator place the participant at unacceptably high risk for participating in the study.
* Hearing impairment in which verbal communication or auditory perception of music is not possible

### 3.2.3 Recruitment

* Surgeons and registrars will be recruited from tertiary hospitals through local hospital emailing lists or national professional bodies
* Medical students will be recruited through the medical school and student organisations through distribution of flyers and emails
* These recruitment materials will direct interested potential participants to seek telephone or email contact with the research team;
* A member of the research team will then answer any questions and forward a Participant Information Sheet. A follow up call or email exchange will be initiated to ascertain if the potential participant meets the inclusion criteria (outlined in the Participant Information Sheet) and agrees to participate, an appointment for the experimental study visit will be booked.

### 3.2.4 Consent

A member of the research team will obtain written informed consent using the Consent Form. A Participant Information Sheet will be given to each potential participant prior to recruitment and the risks and benefits of participating in the study will be clearly explained (as described above). The participant will be given ample time to read the information sheet and the opportunity to enquire about details on the study. All questions or concerns should be answered to the satisfaction of the participant. It will be explained that they are free to decline to take part and will be informed about their right to withdraw from the study at any time. If the individual agrees to take part in the study they will be asked to sign and date the Consent Form that will also be signed and dated by the Investigator. Throughout the study the individual will have the opportunity to ask questions about the study and any new information that may be relevant to the participant’s willingness to continue participation in the study will be shared in a timely manner allowing them to opt out.

## 3.3 Study visits

### 3.3.1 Familiarisation / screening visit

An initial familiarisation visit will be conducted (~45 min) where an investigator will explain the nature of the procedures, answer any questions and obtained written informed consent (as described above). Subsequently, anthropometric (height, weight, hip-to-waist ratio), demographic, clinical information will be collected (Health Screening Questionnaire attached).

At a participants request, this familiarisation visit could in the same sitting as the experiment session.

### 3.3.2 Study 1: Experimental protocol

Participants (surgeons and students) will attend the laboratory for one experimental visit (~2 hours). Experimental sessions will be conducted at the Human Physiology Laboratory, Department of Physiology, Faculty of Medicine and Health Sciences, University of Auckland. Participants will withhold their morning medications until the end of the experimental session in order to limit confounding effects. The procedures will be reviewed again with the participant and remaining questions answered. Prior to the study visit participants will have been provided with a participant information leaflet, advising them of the following pre-study stipulations:

* No food intake for 2 hours prior to the study.
* No caffeine (e.g., coffee, coke, red bull) for 12 hours before the study.
* No alcohol on the day before the study and the day of the study.
* No exercise after 8:00pm the evening before the study and no exercise on the day of the study.
* No ‘over the counter’ (e.g. paracetamol) or cardioactive medications (beta-blocker, ACE inhibitor, angiotensin receptor blockers, calcium antagonists, diuretics (e.g., spironolactone), alpha blockers) on the morning of the study. Patients are advised to bring these medications [if needed to,] to the study appointment so they can take the usual medication immediately after the research tests (by late morning).

Participants will be asked to sit in an upright position on a bed with a table overlying their lap within arm’s reach, adjusted to a comfortable working height. Following this, participants will be instrumented for monitoring of heart rate (by ECG), BP, respiration (through a sterile breathing apparatus), cerebral flow (through non-invasive trans-cranial doppler), and skin conductance. The participants will wear noise cancelling headphones throughout each recording.

Participants will be trained to perform a complex surgical task involving suturing a surgical model and/or a laparoscopic box trainer. Once they have completed the training period, they will be asked to perform the task four times – and will be block randomised to two sessions in the music condition and two sessions in the control condition. The music condition will be at a volume and genre to be selected by the participant. The control condition will be ambient theatre noise (pre-recorded) at a low volume.

Task time to completion will be measured on a stopwatch in minutes/seconds. Following each of the four task performances, photographs of the surgical task will be taken. Participants will then be asked to record answers to two questionnaires (Surgical Task Load Index (SURG-TLX) and State Trait Anxiety Inventory (STAI-6)) and subjectively self-assess their work.

## 3.4 Data analysis

### 3.4.1 Data analysis

Analogue signals for ECG, BP, skin conductance, transcranial doppler and respiration will be sampled simultaneously, and beat-to-beat or breath-by-breath time series derived, before averages are calculated for each experimental period (ADInstruments). Heart rate variability will be calculated post-hoc using Kubios™ software including metrics from Time and Frequency domains. The SURG-TLX score is across 6 parameters each with a score between 0-21. The STAI-6 is also across 6 parameters collected using a Likert scale. Photographs of the surgical task at completion will be taken and three blinded assessors will grade all collected photographs for neatness.

### 3.4.2 Statistical analyses

Anthropometric (e.g., BMI) and demographic (e.g., age) information gathered at primary screening will be quantified using basic statistics (mean, SD, Median, IQR) and graphical presentations (boxplots, histograms, scatter plots). Likewise levels of primary and secondary outcomes will be similarly reported. Normal distribution will be evaluated using Shapiro-Wilk tests. Comparisons of normally distributed physiological variables between groups will be made using a t-test, and non-normally distributed data evaluated using a Mann–Whitney U test. In the event of potential confounding differences in baseline characteristics, analysis of covariance (ANCOVA) will be employed. Statistical analysis will performed using SPSS (IBM). Significance will be set at p < 0.05. Normally distributed data will be presented as mean (SD) while non-normally distributed data will be presented as median [interquartile range].

### 3.4.3 Size of sample

The number of participants required to determine whether cardiovagal function is increased in operating surgeons while listening to music (Aim 1) was calculated on the basis of Umetani et al, who reported a mean +/- SD for RMSSD of 34 +/-13 in 44 male subjects aged 30-49 years old25. Based on these values, a sample size of 18 participants – participating in both arms of the crossover trial operations would yield a minimal detectable difference of 12ms between each group at 80% power and 5% alpha. This is equivalent to a 35% difference between the music and non-music groups.

# 4 RESPONSIVENESS TO MĀORI

## 4.1 Potential benefit to Māori

## 4.2 Management of cultural issues

The researchers understand the importance of appropriate communication with Māori participants. We acknowledge that kanohi ki te kanohi is the most effective recruitment tool in Māori. When recruiting in studies such as this, research staff will always arrange an initial face to face meeting with the participants. Participants are also invited to bring whānau with them to this meeting. This meeting gives participants the opportunity to discuss the study and ask any questions they may have before deciding whether they would like to be involved. Participants will be given as much time as they need to consider participation in the study, including time to discuss with whānau. The protection of taonga of health and information are of primary importance in this study. The researchers recognise that knowledge belongs to the tangata whenua, and must not be removed or handed on without their express approval. Taonga is protected in this study through informed consent, confidentiality of patient information and approval by the Ethics Committee.

## 4.3 Study consultation process

The planning and conduct of the investigators research program has been critically informed by several sources in terms of Māori responsiveness. In the first instance this has been provided by the ‘Responsiveness to Māori (R2M) team' sitting within the Office of the Tumuaki, Faculty of Medical and Health Sciences, University of Auckland.

The investigators are affiliated with the new Centre of Heart Research (Manaaki Mānawa) which is a strategic investment priority of the University of Auckland. At the core of the Centre’s governance structure is a Māori Advisory Committee which has broad representation across clinical and academic disciplines. The investigators will provide regular updates on the progress of their research to the Advisory Committee and draw on their expertise and networks to identify effective ways to share our findings with Māori communities including iwi.

# 5 ETHICAL AND REGULATORY CONSIDERATIONS

## 5.1 Assessment and management of risk

The protocols and physiological measures used in this project are well established and used in research laboratories around the world. The research team are experienced with all the procedures employed (e.g. 26-31). Therefore, the risks associated with the study are low. To further minimise the risk associated with this investigation, studies will be undertaken in a dedicated clinical research laboratory at The University of Auckland, with medically trained personnel in close proximity, along with crash cart facilities, in the unlikely event that they are required.

All of the instruments used to capture outcomes are non-invasive means of measurement. There may be slight discomfort with application of ecg stickers, tightness associated with the blood pressure cuff or the trans-cranial doppler apparatus. The intervention of music through headphones is also non-invasive, and would be a kin to sitting at a computer desk for 2 hours.

Participants will be utilising surgical instruments to suture models as the surgical task. These are non-biological models. There is a small risk of needle-stick injury with handling the surgical sharps, however the blood transmission risk is nil.

The potential risks of microneurography include a brief tiredness in the leg after the procedure. There is also a potential risk of temporary pins­and­needles sensation or increased sensitivity to touch in the leg following microneurography, which subsides after 24­48 hours. However, these side effects are infrequent, affecting approximately 1 in 10 participants. Since 1979, nerve recordings have been performed on thousands of subjects throughout the world (Europe, United States, South America, and Australasia) without complications. One of the co-investigators has previously performed nerve recordings in approximately 200 subjects without complications.

## 5.2 Data protection and patient confidentiality

The participants name (i.e., a direct identifier) will appear on the Consent Form. Participants will be coded with a Participant Information Number and this will be used to store the other study data in a deidentified format. Consent Forms will be maintained at the University of Auckland in a locked filing cabinet in a department with security-limited access, along with all paper records (e.g., health history forms). De-identified coded data in an electronic format will be kept on secure and password protected University of Auckland servers. This electronic data includes the physiological signals (e.g., ECG, BP, skin conductance, respiration and blood vessel function). Once deidentified the risk of reidentification is extremely low. Access to paper and electronic records will be restricted to the researchers, along with the Sponsor, regulatory authorities and the Health and Disability Ethics Committee. Analysis will take place by the study team led by Dr Anantha Narayanan (using deidentified data). No health data will be transferred to individuals in another country.

In accordance with New Zealand law, study data (paper and electronic) will be securely stored for a minimum period of ten years after which they will be destroyed. Paper records will be maintained at the University of Auckland in a locked filing cabinet in a department with security-limited access. De-identified coded data in an electronic format will be kept on secure and password protected University of Auckland servers.

## 5.3 Research ethics committee review and reports

Before the start of the study, approval will be sought from the Health and Disability Ethics Committee (HDEC) for the study protocol, informed consent forms and other relevant documents (e.g., advertisements). Substantial amendments that require review by HDEC will not be implemented until the HDEC grants a favourable opinion for the study. All correspondence with the HDEC will be retained. The Chief Investigator’s will produce the annual reports as required and notify the HDEC of the end of the study.

Authorisation for this study also be obtained by the Sponsor (University of Auckland), and research approval will also be obtained by the Auckland DHB Research Review Committee.

## 5.4 Peer review

This study has been extensively discussed and is supported by a multidisciplinary team who has a specific interest in this population. The quality of this research study has also been assessed and approved by several independent scientific reviewers during the process of receiving competitively awarded funding from Royal Australasian College of Surgeons (RACS) Scholarship and Grants Committee. As such, the study has undergone high quality peer review that is independent, expert and proportionate in accordance with HDEC guidelines.

## 5.5 Protocol compliance

Accidental protocol deviations will be documented and reported to the Chief Investigator immediately. Frequently recurring protocol deviations will not be accepted and appropriate action taken.

## 5.6 Amendments

In the event that an amendment to the protocol is required an application to the HDEC will be submitted in accordance with the latest guidelines. The amendment history will be tracked in the Study Protocol appendix.

# 6. FINANCE

## 6.1 Funding

Funding for this study is provided by the RACS and a Specialty Trainees of New Zealand Research Grant. This will provide a PhD student funding to undertake the project and running costs. All the required scientific equipment is available.

## 6.2 Reimbursement to participants

Travel expenses and subsistence (to cover meal/beverages) will be provided to the participants in the form of a voucher ($50) for each experimental session undertaken.

# 7 DISSEMINIATION POLICY

## 7.1 Dissemination policy

The sponsor owns the data arising from the study and has responsibility for its dissemination. The study findings will be made freely available to the broader scientific community as soon as possible. An electronic copy of each paper that is accepted for publication in a peer-reviewed journal will be deposited within PubMed Central, within 6 months of publication. Participants that express an interest will be notified of the results of the study (e.g., by provision of the publication or bespoke presentation).

## 7.2 Authorship eligibility guidelines

### 7.2.1. Definition of authorship

An author is considered to be someone who has made substantive intellectual contribution to a study. Many journals consider it best practice that everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work. Honorary or guest authorship is not acceptable.

### 7.2.2. Procedure

 The baseline criteria for this research for both authorship and acknowledgments for peer reviewed publications and conference contributions is that:

**i.** Authors must meet all of the following criteria:

* substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
* drafting the article or revising it critically for important intellectual content
* final approval of the version to be published

**ii.** No-one should be omitted from the authorship list if he/she meets the three criteria in ‘i’ above.

**iii.** Some journals allow authorship of multi-centre projects to be attributed to a group. However, all members of the group who are named as authors must still fully meet the above criteria for authorship in ‘i’ above.

**iv.** Other collaborators or members of the research group who may have contributed to some but not all of the criteria in ‘i’ above will be listed in the Acknowledgments (see vi below).

**v.** The individual authors will jointly make decisions about authorship before submitting the manuscript for publication. The lead author, corresponding author or the guarantor must be prepared to explain the presence and order of these individuals to the editor of a journal. Authorship and order of authorship (see 7 below) will be agreed in advance, in the early stages of the research.

**vi.** All contributors who do not meet the criteria for authorship will be listed in an Acknowledgments section. Examples of those who might be acknowledged include:

* persons who have contributed materially to the paper but whose contributions do not justify authorship. These may be listed under such headings as “participating investigators” and their function or contribution should be described - for example, “served as scientific advisors,” “critically reviewed the study proposal,” or “collected data/material”. Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged
* a person who provided purely technical help, provided general comments on the manuscript or writing assistance, or a departmental chair who provided general support
* editors can ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. Authors should therefore disclose in the Acknowledgements section the identity of any individuals who provided this assistance and any entities that supported the work in the published article
* financial support should also be acknowledged and, if appropriate, the grant identified
* material or logistical support, in particular giving recognition to support provided in developing countries, should always be acknowledged

**vii.** Order of authorship

* the authors shall decide the order of authorship together. Contributors should discuss authorship issues frankly at the start of the work for each anticipated publication and not wait to raise concerns at submission time
* authors shall specify in their manuscript a description of the contributions of each author and how they have assigned the order in which they are listed so that readers can interpret their roles correctly
* the corresponding author or guarantor shall prepare a concise, written description of how the order of authorship was decided
* examples of authorship order include:
* descending order of contribution
* placing the person who took the lead in writing the manuscript or doing the research first and the most experienced contributor in the field last
* alphabetical
* random order

**viii.** If an individual leaves the project the question of contribution to publications and authorship should be discussed in advance of their departure to minimise misunderstandings and to agree how this will be managed.

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# 9 APPENDIX

## 9.1 APPENDIX 1: Amendment History

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| Amendment number | Date of Amendment | Protocol version number | Summary of Amendment |
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