ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
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ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	REB 2020-068
Brief Title:	The Effects of Music & Auditory Beat Stimulation on Anxiety
Official Title:	The Effects of Music & Auditory Beat Stimulation on Anxiety
Secondary IDs:	

Study Status

Record Verification:	November 2021
Overall Status:	Completed
Study Start:	July 9, 2020 [Actual]
Primary Completion:	February 2, 2021 [Actual]
Study Completion:	February 2, 2021 [Actual]

Sponsor/Collaborators

Sponsor:	Ryerson University
Responsible Party:	Principal Investigator Investigator: Frank Russo [frusso] Official Title: Professor Affiliation: Ryerson University
Collaborators:	Lucid, Inc. Mitacs

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: REB 2020-068 Board Name: Ryerson University Research Ethics Board Board Affiliation: Ryerson University Phone: 4169795000 Email: rebchair@ryerson.ca Address: Office of the Vice-President, Research & Innovation

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Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Anxiety is a growing problem and has been steadily increasing, particularly in the adolescent and young adult populations in the past 24 years. Music and auditory beat stimulation (ABS) in the theta frequency range (4-7 Hz) are sound-based anxiety treatments that have been independently investigated in prior studies. Here, the anxiety-reducing potential of calm music combined with theta ABS was examined in a large sample of participants. Participants taking anxiolytics (n = 163) were randomly assigned to a single 24-minute session of sound-based treatment: combined (music & ABS), music-alone, ABS-alone, or pink noise (control). Pre- and post-intervention somatic and cognitive state anxiety measures (STICSA State) were collected along with trait anxiety (STICSA Trait), personality measures (Short Form Eysenck Personality Inventory) and musical preferences (Short Test of Music Preferences).

Detailed Description: In this study, the investigators examined and compared the effectiveness of ABS in the theta range, calm music playlist curated by an affective music recommendation system, and the combination of ABS and the same music to reduce anxiety and stress levels (as measured by the State Trait Inventory for Cognitive and Somatic Anxiety (STICSA)) compared to a control condition (pink noise). Prior work has demonstrated that ABS and music both reduce anxiety when presented on their own. It is hypothesized that music with ABS will lead to significantly lower anxiety levels and increased calmness compared to the other experimental conditions. Approximately 163 participants were recruited from the Prolific online participant pool (https://www.prolific.co). The experiment was conducted on the Qualtrics survey platform, and the experimental treatment was provided with the LUCID Research App. After reading and agreeing with the consent form, participants provided their Prolific ID and then filled out the Short Test of Music Preferences (STOMP), Queen's Music Questionnaire, Anxiety coping method's questionnaire, were asked to list any medications they are currently taking (including cannabis) and completed the Positive and Negative Affect Scale (PANAS), Self-Assessment Manikin (SAM), Eysenck Personality Questionnaire and the State Trait Inventory of Cognitive and Somatic Anxiety (STICSA) trait and state questionnaires. Participants were then randomly assigned to one of four treatment groups where they listened to either music, music and auditory beat stimulation (ABS), auditory beat stimulation (ABS) alone, or pink noise for 24 minutes. Participants then received instructions on how to download the LUCID Research app on their iOS device or access the LUCID Research App through a virtual machine using their computer. Participants listened to their randomly assigned treatment for 24 minutes. Participants then completed their post-intervention questionnaires which included: the STICSA state version, SAM and PANAS. The investigators' hypotheses were that the combined, music alone and ABS alone conditions would experience a greater reduction in somatic and cognitive state anxiety compared to the pink noise control condition. These hypotheses were pre-registered using the Open Science Framework (Registration DOI: https://doi.org/10.17605/OSF.IO/VHCA5) and were based upon previous studies showing that ABS and music listening are capable of reducing anxiety. The investigators had no specific predictions for moderate and high trait anxiety participants, but their pre-registration noted their intention to recruit from both of these populations.

Conditions

Conditions:	Anxiety
Keywords:	Anxiety Auditory Beat Stimulation Binaural Beats Mental Health Music Neuroscience Psychology

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment Parallel Assignment Participants taking anxiolytics (n = 163) were randomly assigned to a single 24- minute session of sound-based treatment: combined (Music with theta auditory beat stimulation), music-alone, theta auditory beat stimulation-alone, or pink noise (control). Pre- and post-intervention somatic and cognitive state anxiety measures (STICSA State) were collected along with trait anxiety (STICSA Trait), personality measures (Short Form Eysenck Personality Inventory) and musical preferences (Short Test of Music Preferences).
Number of Arms:	4
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	163 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Music & Auditory Beat Stimulation Participants listened to calm music with theta auditory beat stimulation for 24 minutes	Behavioral: Music & Auditory Beat Stimulation Listening to calm music and auditory beat stimulation Participants listened to calm music with theta auditory beat stimulation for 24 minutes
Active Comparator: Music Alone Participants listened to calm music for 24 minutes	Behavioral: Music Alone Listening to calm music Participants listened to calm music for 24 minutes
Active Comparator: Auditory Beat Stimulation Participants listened to theta auditory beat stimulation for 24 minutes	Behavioral: Auditory Beat Stimulation Listening to theta auditory beat stimulation Participants listened to theta auditory beat stimulation for 24 minutes
Sham Comparator: Pink Noise Participants listened to pink noise for 24 minutes	Behavioral: Pink Noise Listening to pink noise Participants listened to pink noise for 24 minutes

Outcome Measures

Primary Outcome Measure:

1. Anxiety: State Trait Inventory for Cognitive and Somatic Anxiety (STICSA)
   The State Trait Anxiety Inventory for Cognitive and Somatic Anxiety has good reliability and validity as a measure of state and trait cognitive and somatic anxiety. The minimum score is 10 and the maximum is 40. Higher scores indicate higher anxiety (worse outcome). But in this study the post-intervention anxiety score is subtracted from the pre-intervention anxiety score, giving a measure of anxiety reduction. In the case of this anxiety reduction measure, higher anxiety reduction scores would indicate a better outcome.

   [Time Frame: 24 minutes]

Secondary Outcome Measure:

2. Mood: Positive and Negative Affect Scale (PANAS)
   The Positive and Negative Affect Scale has good reliability and validity and has been widely used in many studies to assess mood. This scale generates two scores: 1) Positive affect (higher score indicates a better outcome), scores range from 10-50. 2) Negative affect (higher score indicates worse outcome), scores range from 10-50.

   [Time Frame: 24 minutes]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Adults (18+)
- Must be taking anxiety medication
- Self-identified normal hearing
- No known cardiac issues
- No known epilepsy/seizures
    - Have access to an iOS device (iPhone or iPad) to run the Research Application

Exclusion Criteria:

- Adults younger than 18
- Not taking anxiety medication
- Have known cardiac issues

  - Do not have access to an iOS device (iPhone or iPad) to run the Research Application
- Have known epilepsy/seizures

Contacts/Locations

Central Contact Person:	Adiel Mallik, PhD Telephone: 4169795000 Ext. 554989 Email: adiel.mallik@ryerson.ca
Central Contact Backup:	
Study Officials:	Frank A Russo, PhD Study Director Ryerson University

Locations: **Canada, Ontario**

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IPDSharing

Plan to Share IPD: Yes

We have registered the project on Open Science Framework and will make all elements of IPD open to the public. Please see: https://osf.io/efya2/ Study protocol and analysis plan: https://doi.org/10.17605/ OSF.IO/VHCA5 Consent form: https://osf.io/efya2/

Supporting Information:
Study Protocol
Statistical Analysis Plan (SAP)
Informed Consent Form (ICF)

Time Frame:
Data are available now and will be for 7 years post data collection completion as per our REB approval: approximately January 2028

Access Criteria:
There is no specific access criteria for the IPD on OSF. It is freely and openly available to anyone.

URL: https://osf.io/efya2/

References

Citations: Bados A, Gómez-Benito J, Balaguer G. The state-trait anxiety inventory, trait version: does it really measure anxiety? J Pers Assess. 2010 Nov;92(6):560-7. doi: 10.1080/00223891.2010.513295. PubMed 20954057

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Links:

Available IPD/Information:

Type: Individual Participant Data Set
URL: https://osf.io/efya2/

Type: Study Protocol
URL: https://doi.org/10.17605/OSF.IO/VHCA5

Type: Statistical Analysis Plan
URL: https://doi.org/10.17605/OSF.IO/VHCA5

Type: Informed Consent Form
URL: https://osf.io/efya2/

Documents

Study Protocol
Document Date: March 18, 2021
Uploaded: 11/26/2021 16:54

Statistical Analysis Plan
Document Date: March 18, 2021
Uploaded: 11/26/2021 16:57

Informed Consent Form
Document Date: March 18, 2021
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