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Exploring the effect of music listening duration on anxiety reduction

Submission date	Recruitment status	[ ] Prospectively registered
30/04/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/08/2024	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Studies have shown that music can be used in various contexts to reduce anxiety. While the relationship between music and anxiety reduction has been well researched and documented, there is still a need for a controlled study on the relationship between the length of musical treatment and the reduction in anxiety to improve the self-administration of musical interventions. A recent study found that music combined with auditory beat stimulation, relative to music alone, auditory beat stimulation alone or pink noise, was effective at reducing anxiety for individuals with moderate trait anxiety (anxiety as an everyday personality trait). This study seeks to replicate and extend these findings by examining whether the strength of the findings differs depending on the length of the combined music with auditory beat stimulation.

Who can participate?
Patients aged 18 years and over with moderate trait anxiety who were actively taking anxiolytics (medications that can treat anxiety symptoms)

What does the study involve?
Participants were randomly allocated to 12, 24, or 36 minutes of either music with auditory beat stimulation (treatment) or pink noise (control). Participants completed questionnaires before and after the treatment assessing state anxiety and affect.

What are the possible benefits and risks of participating?
This study is a minimal-risk study. However, participants may have felt some discomfort in responding to the questions. To mitigate this, participants were informed that their participation was voluntary and they were able to withdraw at any time. While there were no guaranteed benefits of participating in this study, participants may have experienced a reduction in their anxiety and contributed to the understanding of the relationship between music listening and anxiety relief.

Where is the study run from?
Goldsmith's, University of London (UK)

When is the study starting and how long is it expected to run for?
December 2022 to August 2023

Who is funding the study?
1. LUCID Therapeutics, the developers of the combined music and auditory beat stimulation treatment
2. Goldsmith's, University of London (UK)

Who is the main contact?
Prof. Lauren Stewart, lauren.stewart@roehampton.ac.uk

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
PS130723DMS

Study information

Scientific Title
Dose-response relationship between music and anxiety reduction

Acronym

DRMA

Study objectives
1. Those assigned to the music with auditory beat stimulation (ABS) treatment condition will experience a greater reduction in anxiety relative to those in the pink noise control condition.
2. The duration of music with ABS listened to will have differential effects on anxiety symptoms.
3. Those assigned to the 36-minute music with ABS treatment condition will experience a greater reduction in anxiety than those in the 12- or 24-minute music with ABS treatment conditions.
4. The findings of the present study will replicate those of Malik and Russo (2022).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/07/2023, Goldsmiths, University of London Psychology Department Ethics Committee (8 Lewisham Way, London, SE14 6NW, United Kingdom; +44 (0)20 7919 7171; d.mullensiefen@gold.ac.uk), ref: PS130723DMS

Study design
Single-blind randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Efficacy

Participant information sheet
https://ryersonpsych.co1.qualtrics.com/jfe/preview/previewId/80d1b496-7c8a-4685-a736-0512fb36184b/SV_37ZKptLRPiqHP0O?Q_CHL=preview&Q_SurveyVersionID=current

Health condition(s) or problem(s) studied
Anxiety

Interventions
Participants are recruited and screened through prolific.com. In order to be eligible, participants must self-identify as taking anxiolytic medication and having moderate trait anxiety. Those eligible sign a consent form and are randomized to a condition and a dosage. The conditions are music with auditory beat stimulation (treatment condition) or pink noise (control condition). The dose variations will be listening to the audio for 12, 24, or 36 minutes. Participants will be randomized at a rate of 3:3 using the randomizer function on qualtrics.com.

Intervention Type
Behavioural

Primary outcome measure
State Anxiety is measured using the State Trait Inventory for Cognitive and Somatic Anxiety at baseline and post-intervention (after 12, 24, or 36 minutes)

Secondary outcome measures
Affect measured using the Positive and Negative Affect Scale at baseline and post-intervention (after 12, 24, or 36 minutes)

Overall study start date
14/12/2022

Completion date
12/08/2023

Eligibility

Key inclusion criteria
1. Currently taking anxiolytics
2. Have moderate trait anxiety as defined by previously described State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA) trait anxiety threshold scores

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
120-160

Total final enrolment
144

Key exclusion criteria
1. Do not meet the criteria for moderate trait anxiety
2. Not actively taking anxiolytic medication

Date of first enrolment
17/07/2023

Date of final enrolment
12/08/2023

Locations

Countries of recruitment
Australia

Brazil

Canada

Chile

Djibouti

England

Ireland

Israel

Italy

Malaysia

Mexico

Netherlands

Northern Ireland

Poland

Portugal

Romania

Scotland

South Africa

Spain

United Kingdom

United States of America

Wales

Study participating centre
Goldsmiths' College
Goldsmiths College 8
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SE14 6NW

Sponsor information

Organisation
Goldsmiths University of London

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Sponsor type
University/education

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http://www.gold.ac.uk/

ROR
https://ror.org/01khx4a30

Funder(s)

Funder type
Industry

Funder Name
Lucid Digital Therapeutics

Funder Name
Goldsmiths University of London

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2024

Individual participant data (IPD) sharing plan
The de-identified data that supports the findings of this study will be made available on the Open Science Framework.
The type of data stored: Participant responses to self-reports, including demographic information (nationality, type of medications currently taking) and raw scores on anxiety and affect questionnaires.
Dates of availability: From publication date
Informed consent was required and obtained for all participants.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/05/2024	No	Yes