

Exploring the effect of music listening duration on anxiety reduction

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| Submission date 30/04/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 09/05/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 30/08/2024 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input checked="" type="checkbox"/> 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

Contact name

Prof Lauren Stewart

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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
Lewisham Way
London
United Kingdom
SE14 6NW

Sponsor information

Organisation

Goldsmiths University of London

Sponsor details

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HoD.Psych@gold.ac.uk

Sponsor type

University/education

Website

<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 |