

High-frequency vs low-frequency music therapy in psychiatric inpatients

Submission date 15/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2024	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

This study is comparing two different schedules of music therapy for patients with mental health disorders. It aims to find out if having music therapy sessions more frequently (five times a week) is more effective than having them less frequently (once a week) in reducing symptoms of anxiety, depression, and stress, and in improving overall life satisfaction.

Who can participate?

Adults who have been hospitalized in a mental health unit for at least 48 hours and have recently had their medication adjusted can participate in this study.

What does the study involve?

Participants will be randomly assigned to one of two groups: one group will have music therapy sessions five times a week, and the other group will have sessions once a week. The therapy sessions include activities like Progressive Muscle Relaxation and using various musical instruments and tools to encourage creativity and relaxation. Participants will complete questionnaires about their symptoms before and after the therapy.

What are the possible benefits and risks of participating?

The possible benefits include reduced symptoms of stress, anxiety, and depression. However, there are some risks, such as the therapy potentially bringing up negative memories, creating a sense of strangeness, or causing mental fatigue due to the repetition of sessions.

Where is the study run from?

The study is being conducted at ICSN - Clínica Montserrat in Bogotá, Colombia

When is the study starting and how long is it expected to run for?

July 2024 to September 2024

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Manuel-F Esteban-Cárdenas, mestebanc@unbosque.edu.co

Contact information

Type(s)

Principal Investigator

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information**Scientific Title**

High vs low-frequency music therapy in psychiatric inpatients: A randomized, controlled clinical trial

Acronym

HILOM-PSY

Study objectives

Patients receiving high-intensity music therapy (5 sessions per week) show a significantly greater reduction in anxiety, depression and stress levels, greater overall life satisfaction and a greater perceived impact of music therapy sessions, compared to patients receiving low-intensity music therapy (1 session per week).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 26/07/2024, C.E.I Campo Abierto LTDA (Carrera 53 #104B-35 Office 706, Bogotá D.C, 111111, Colombia; +57 3106974943; eticaeninvestigacion@hotmail.com), ref: Acta 209

Study design

Single-center interventional randomized and controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life, Treatment, Efficacy

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Anxiety, depression, stress, general life satisfaction and perceived impact of music therapy in psychiatric inpatients.

Interventions

This is a randomized controlled clinical trial. Participants were randomly assigned with a 1:1 ratio to either the high-frequency music therapy intervention group or the low-frequency control group. Randomization was performed by random number generation. The high-frequency intervention group received five sessions of music therapy in one week of inpatient treatment at a rate of one session per day for five consecutive days. The low-frequency control group received one music therapy session in one week of inpatient treatment.

Intervention Type

Behavioural

Primary outcome measure

Symptoms of depression, anxiety and stress measured using the liked scale: Depression Anxiety Stress Scale of 21 items (DASS-21) at baseline and follow up

Secondary outcome measures

1. Overall life satisfaction measured using Single Item Life Satisfaction Measurement at baseline and follow up
2. Impact of music therapy sessions on adult patients measured using [CISMA-scale] at baseline and follow up

Overall study start date

26/07/2024

Completion date

11/09/2024

Eligibility

Key inclusion criteria

1. Individuals over 18 years of age
2. More than 48 hours of psychiatric hospitalization at the time of recruitment
3. Pharmacological treatment with medication adjustments in the last two weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

74 Years

Sex

Both

Target number of participants

70

Total final enrolment

74

Key exclusion criteria

1. Previous participation in music therapy programs
2. Main diagnosis of hospitalization abstinence syndrome or substance dependence
3. More than six days of hospitalization at the time of selection

Date of first enrolment

01/08/2024

Date of final enrolment

01/09/2024

Locations**Countries of recruitment**

Colombia

Study participating centre

Instituto Colombiano del Sistema Nervioso-Clinica Monserrat

Carrera 71, Cl. 134 #17, Usaquén

Bogotá D.C

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Sponsor information

Organisation

Instituto Colombiano del Sistema Nervioso-Clinica Montserrat

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Sponsor type

Hospital/treatment centre

Website

<https://clinicamontserrat.com.co/>

Organisation

Universidad El Bosque

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Sponsor type

University/education

Website

<https://www.unbosque.edu.co>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

15/11/2024

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be stored in a publicly available repository
OpenScienceFramework
<https://osf.io/384fb/>

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			13/11/2024	No	No