

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

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| <b>Submission date</b><br>15/10/2024   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered               |
|  |   | <input checked="" type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>21/11/2024 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan              |
|  |   | <input type="checkbox"/> Results                                |
| <b>Last Edited</b><br>13/11/2024       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data            |
|  |   | <input checked="" type="checkbox"/> Record updated in last year |

## Plain English Summary

### 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 hypothesis

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

### **Condition**

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

### **Overall study end date**

11/09/2024

## **Eligibility**

### **Participant 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

**Participant 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

**Recruitment start date**

01/08/2024

**Recruitment end date**

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

Colombia

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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

**Sponsor details**

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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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> |         |              | 13/11/2024 | No             | No              |