

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

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| 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 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

Contact name

Dr Manuel Esteban Cardenas

ORCID ID

<https://orcid.org/0000-0002-8516-6151>

Contact details

Carrera 53 #134a-47 Bogotá.Colombia
806

Bogota D.C

Colombia

111111

+57 3057532484

mestebanc@unbosque.edu.co

Type(s)

Scientific

Contact name

Dr Eugenio Ferro

ORCID ID

<https://orcid.org/0000-0002-2127-7696>

Contact details

Calle 134 #17-71

Bogotá D.C

Colombia

110121

+57 3106182238

eugenio.ferro@icsn.co

Type(s)

Public

Contact name

Dr Ana Gomez

ORCID ID

<https://orcid.org/0009-0000-3502-0253>

Contact details

Calle 134 #17-71
Bogotá D.C
Colombia
110121
+57 3238129463
amagomez@unbosque.edu.co

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Quality of life, Treatment, Efficacy

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

74 years

Sex

All

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

Colombia

110121

Sponsor information

Organisation

Instituto Colombiano del Sistema Nervioso-Clinica Montserrat

Organisation

Universidad El Bosque

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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 |