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

Submission date
15/10/2024

Recruitment status
No longer recruiting

Registration date
21/11/2024

Overall study status
Completed

Last Edited
20/04/2026

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Additional identifiers

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

Primary study design
Interventional

Study design
Single-center interventional randomized and controlled trial

Study type(s)
Efficacy, Quality of life, Treatment

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
Mixed

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
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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?
Results article		17/04/2026	20/04/2026	Yes	No
Protocol file			13/11/2024	No	No