Feasibility of intensive group music therapy

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
03/04/2017		[X] Protocol		
Registration date 04/04/2017 Last Edited	Overall study status Completed Condition category Mental and Behavioural Disorders	Statistical analysis plan		
		☐ Results		
		Individual participant data		
27/05/2025		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

This study involves people admitted to hospital for assessment and treatment of mental health problems (acute psychiatric in-patient care). People are admitted if they are experiencing a crisis in their mental health and are at risk of harm. The person may not have experienced mental health problems before or may have symptoms that have become worse. Admission to hospital can be a frightening experience and the person may be admitted against their will (sectioned). During hospital admission, assessments are made by different health-care professions. Medication is prescribed along with access to groups and psychological therapy which aims to support the person in their recovery and to return home as quickly as possible. Music therapy is one form of arts therapy that is often provided in groups in hospitals. The study team has developed an approach to music therapy which is provided four times per week for people in hospital for mental health problems. In order to conduct a study to find out how effective the approach is, it is important to conduct a small study to find out how best to do this so that we can make sure this is done properly and is acceptable to people who take part. The aim of this study is to find out if it is feasible to conduct a research study in this area.

Who can participate?

Adults who have been admitted to hospital for assessment and treatment of mental health problems.

What does the study involve?

The study has two parts. In part one, adults on four hospital wards are invited to participate. If they agree to take part, the researcher goes through an initial assessment and ask questions about symptoms, interest in music, mood, relationships with others and satisfaction with treatment. After this assessment, participants are randomly allocated to one of two groups. Those in the first group attend an off-ward music therapy group for 60 minutes, 4 times per week for up to 4 weeks. Those in the second group continue to receive usual care, which involves being able to access all other care provided in hospital apart from music therapy. In part two, adults on two wards, admitted to hospital are invited to participate. One ward has an on-ward music therapy group that runs for 3 times per week. At the other ward does not have music therapy input. Patients on both wards are invited to take part as above to complete the assessments only.

In both parts of the study, the initial assessments are repeated after two and four weeks and three and six months. An optional interview is offered at four weeks for participants to tell the researchers what their experience of taking part in the study and music therapy was like.

What are the possible benefits and risks of participating?

There are no guaranteed benefits involved with taking part, however existing research into music therapy for people in hospital with mental health problems suggests it might help with motivation, symptoms, mood and relationships. Participants may value being able to share their experiences to provide information on how to improve group music therapy in hospitals. There is a small risk that in music therapy some people find the music in the group noisy or upsetting. In addition, participants might find it difficult to read the questionnaires. The researcher can help if this is the case. Some of the questions might cause discomfort or upset.

Where is the study run from?

- 1. Newham Centre for Mental Health (UK)
- 2. Tower Hamlets Centre for Mental Health (UK)

When is the study starting and how long is it expected to run for? April 2016 to August 2018

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Catherine Carr c.e.carr@qmul.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Catherine Carr

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

34200

Study information

Scientific Title

Feasibility study for a randomised controlled trial of intensive group music therapy for acute adult psychiatric inpatients (F-IGMT)

Acronym

F-IGMT

Study objectives

The aim of this study is to assess the feasibility of conducting a larger effectiveness study of music therapy in reducing mental illness symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London-Fulham Research Ethics Committee, 30/03/2017, ref: 17/LO/0505

Study design

Randomised; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Study not assigned to a MH Clinical Studies Group; UKCRC code/ Disease: Mental Health/ Unspecified mental disorder

Interventions

Stage 1:

Participants are randomised individually to receive music therapy or treatment as usual in a 2:1 ratio.

Music therapy: Participants receive off-ward group music therapy, 60 minutes, 4 times per week for up to 4 weeks

Treatment as usual: Participants receive all other medical and therapeutic care offered within the hospital

In both groups, participants undergo follow up assessments at two and four weeks and three and six months, with an optional semi-structured interview at four weeks.

Stage 2:

Simulation of cluster randomisation comparing one ward with music therapy input to one ward without.

Music therapy ward: Participants receive on-ward group music therapy, 60 minutes, 3 times per week for up to 4 weeks

Control ward: Participants receive all other medical and therapeutic care offered within the hospital.

In both groups, participants undergo follow up assessments at two and four weeks and three and six months, with an optional semi-structured interview at four weeks.

Intervention Type

Other

Primary outcome measure

Feasibility outcomes:

- 1. Recruitment rate is recorded as the number of eligible participants who consent to participate in the study by 10 weeks
- 2. Participation rate is recorded as the proportion of eligible participants who consent to participate by 10 weeks.
- 3. Retention rate is recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 6 months
- 4. Compliance rate is recorded as the number of participants allocated to the intervention arm who attend 10 or more sessions of music therapy within 4 week treatment period

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2016

Completion date

31/08/2018

Eligibility

Key inclusion criteria

- 1. Adults aged 18 or above, any gender, admitted to and receiving treatment on an acute psychiatric ward
- 2. Willingness to receive group music therapy or treatment as usual
- 3. Willingness to be randomised to group music therapy or treatment as usual (stage 1, off-ward recruitment only)
- 4. Capacity to give informed consent
- 5. Sufficient English language comprehension to complete measures, or access to assistance from an interpreter

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

- 1. Presence of an organic mental disorder
- 2. Insufficient language comprehension and no available interpreter
- 3. No capacity to give informed consent (monitoring of capacity will occur throughout)

Date of first enrolment

10/04/2017

Date of final enrolment

07/08/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Newham Centre for Mental Health

Glen Road London United Kingdom E13 8SP

Study participating centre Tower Hamlets Centre for Mental Health

Bancroft Road London United Kingdom E1 4DG

Sponsor information

Organisation

Queen Mary University of London

Sponsor details

Joint Research Management Office 5 Walden Street London England United Kingdom E1 2EF +44 20 7882 7260 sponsorsrep@bartshealth.nhs.uk

Sponsor type

University/education

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

- 1. Planned publication in a high-impact peer reviewed open access journal
- 2. Dissemination of findings to study participants and carers
- 3. Dissemination to local NHS Trusts, professional bodies and charities

Intention to publish date

31/08/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other files	End of study Summary	27/05/2025	27/05/2025	No	No
Protocol file	version 5	03/03/2017	27/05/2025	No	No