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Group music therapy for chronic depression

Submission date	Recruitment status	[X] Prospectively registered
26/09/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Chronic depression is a term used for depression that lasts for more than two years. Treating chronic depression is challenging: frequent relapses can be demoralising for patients and carers, and has high healthcare costs. Music therapy aims to support health, using therapeutic relationships and musical activities with verbal reflection. Studies support music therapy for reducing depression symptoms however research is lacking for groups in the NHS. The aim of this study is to find out whether conducting a large study looking at the effectiveness of music therapy for chronic depression is feasible.

Who can participate?
Adults with chronic depression who have been receiving treatment for at least 12 months

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are invited to a community centre to take part in group music therapy three times a week for 14 weeks. The therapy sessions last for around 90 minutes each and focus on songwriting as a means of supporting well-being. Participants in the second group continue as normal for the duration of the study. At the end of the study period, these participants are offered the group music therapy. All participants complete interviews and questionnaires to assess their symptoms of depression, lifestyle, interest in music and functioning at the start of the study, and 1, 3 and 6 months later. In addition, the investigators access medical records to calculate overall costs of care.

What are the possible benefits and risks of participating?
Given the existing research supporting group and individual music therapy for those with depression in other countries, participants may find group music therapy helpful with the symptoms of depression and general wellbeing. However given this type of research has yet to be conducted in the UK with this type of group we cannot guarantee any such benefits to participation. Participants may benefit in the knowledge that their experiences and views will help us determine how feasible it would be to run a larger study of music therapy and inform us as to what benefits we might wish to measure in this study.

There are not expected to be any major disadvantages or risks to taking part in this study. The main disadvantages are taking time to attend meetings with the researcher and the possibility that participants feel uncomfortable or upset answering questions or that making music could remind them of painful memories.

Where is the study run from?
Newham Centre for Mental Health (UK)

When is the study starting and how long is it expected to run for?
April 2016 to September 2017

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

Who is the main contact?
Dr Catherine Carr
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Contact information

Type(s)
Scientific

Contact name
Dr Catherine Carr

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31529

Study information

Scientific Title
StudY oN group music therapy for CHRONic depression: an exploratory pilot to assess feasibilitY of a randomised controlled trial with wait-list control

Acronym
SYNCHRONY

Study objectives
The aim of this study is to pilot group music therapy for patients with chronic depression and assess the feasibility of conducting a larger randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 2, 13/09/2016, ref: 16/WA/0248

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Depression; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

Interventions
Participants will be randomised individually with unbalanced allocation to the intervention and control groups (2:1).

Intervention group: Participants undertake group music therapy. The treatment will take a songwriting focus and will run for 14 weeks, 3 times per week in a community location. The groups will be run by 2 HCPC registered qualified music therapists. Up to 10 participants will be in each group.

Control group: Participants are placed on a waiting list for the duration of the intervention.

All study participants will complete interviews and questionnaires to assess their symptoms of depression, lifestyle, interest in music and functioning at the start of the study, and 1, 3 and 6 months later. Follow up interviews will take place at the researcher's workplace (The Unit for Social and Community Psychiatry), at a Community Mental health Team base in Newham, or a location convenient to the participant

Intervention Type
Other

Primary outcome measure
1. Acceptability of methodology to professionals and patients is determined through review of recruitment rates, compliance rates and interviews at 6 months post-intervention
2. Feasibility of recruitment processes is determined through assessing recruitment rate at study end
3. Eligibility, participating and retention rates are measured through screening, recruitment and attendance logs at study end
4. Researcher time and costs per participant is assessed using researcher time diaries at study end
5. Feasibility of the intervention is measured by reviewing attendance rates of participants, use of components by therapists throughout the intervention period of 14 weeks, and adherence to the intervention manual by therapists in the same period
6. Acceptability of the intervention is measured by the estimation of likely intervention effect after 14 weeks, 1, 3 and 6 month follow-ups across the measures of symptoms of: depression, psychological distress, social functioning, self-esteem, self-efficacy, satisfaction with treatment, work and social adjustment, service use and quality of life

Secondary outcome measures
1. Observer rated depression is measured at baseline, 1, 3 and 6 months post-intervention
2. Self-reported depression is measured at baseline, 1, 3 and 6 months post-intervention
3. Psychological distress is measured at baseline, 1, 3 and 6 months post-intervention
4. Social functioning is measured at baseline, 1, 3 and 6 months post-intervention
5. Self-esteem is measured at baseline, 1, 3 and 6 months post-intervention
6. Self-efficacy is measured at baseline, 1, 3 and 6 months post-intervention
7. Mood is measured using The Dispositional Mood Scale at pre and post session
8. Relationships are measured using Relationship Satisfaction Scale (RSS)(weekly, session 2, pre & post)
9. Satisfaction with treatment is measured at baseline, 1, 3 and 6 months post-intervention
10. Work and social adjustment is measured at baseline, 1, 3 and 6 months post-intervention
11. Hospitalisation is measured at baseline, 1, 3 and 6 months post-intervention
12. Quality of Life is measured at baseline, 1, 3 and 6 months post-intervention

Overall study start date
01/04/2016

Completion date
30/09/2017

Eligibility

Key inclusion criteria

1. Adults aged 18 or above
2. Confirmed diagnosis of depression (ICD10 F31-39, F20.4, F43)
3. Receiving treatment for depression 12 months or longer
4. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
30

Key exclusion criteria
1. Diagnosis of organic mental disorder (ICD10 F00-09)
2. Bipolar affective disorder- current manic episode
3. No capacity to give informed consent
4. Risk of suicide necessitating hospitalisation

Date of first enrolment
01/10/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newham Centre for Mental Health
Glen Road
London
United Kingdom
E13 8SP

Sponsor information

Organisation
East London NHS Foundation Trust (Noclor)

Sponsor details
1st Floor, Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q0vs094

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

The CI, co-applicants and Service User Lead will consult with each other as to a strategy for dissemination, and will at all times ensure they meet the standards required for submission to high quality peer reviewed journals etc. Data arising from the trial will be owned by the Unit for Social and Community Psychiatry. On completion of the trial, the final data will be analysed and tabulated and a Final Study Report prepared. Participants will be informed of the results of the study via a specifically designed newsletter. Participants may request specific results relating to their participation from the CI or Trial Co-ordinator once the study results have been published and members of the TMG are un-blinded.

Intention to publish date

30/09/2019

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?
Protocol article	protocol	29/03/2017		Yes	No
Results article		05/05/2023	09/05/2023	Yes	No
HRA research summary			28/06/2023	No	No