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Effectiveness of group arts therapy for mixed diagnosis community mental health patients

Submission date
30/08/2018

Recruitment status
No longer recruiting

Registration date
12/09/2018

Overall study status
Completed

Last Edited
22/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Arts therapies use different art forms and creative activities to help people living with mental illness. These include music therapy, dance-movement therapy and art therapy. They are usually provided in regular group meetings over a few months. Arts therapies may help patients to express emotions and have experiences that might not be possible in talking therapies.
Different people prefer different art forms. If patients can choose which art form they like best, they may be more likely to attend and benefit from this. While arts therapies are popular with many patients, they are not always provided in NHS services. So far, there has been little research to show that they are helpful. Existing research has involved people with only one diagnosis (such as schizophrenia). This is different to how arts therapies groups are provided, as they usually include people with different mental illnesses.
This study aims to test if arts therapies groups are effective for patients with different types of mental illness.

Who can participate?
Adult patients with a main diagnosis of schizophrenia, depression or anxiety, in community mental health services who are currently finding their symptoms difficult

What does the study involve?
Participants will be divided in two groups randomly. Half will receive their preferred form of arts therapy group, which could be art, dance or music. The other half will be offered group meetings with general talking and support, but no use of arts. Patients can attend for up to 40 sessions over 5 months. We will interview patients at the beginning and end of treatment, 6 and 12 months later. We will then compare the two groups to see if patients receiving arts therapies had a better improvement of symptoms and quality of life. There will also be optional interviews about patient experiences with the therapy.

What are the possible benefits and risks of participating?
Current research suggests that group therapy can be helpful to meet others who are in a similar situation. Groups can be a useful source of support. Research suggests that arts therapies are enjoyable and can be helpful to express feelings and interact with others. Some research suggests that arts therapies can help with symptoms, but we cannot guarantee this.

Some people feel worse before they start to feel better in group therapy. Using the arts can sometimes put us in touch with painful feelings or memories that can feel overwhelming. If any of this happens during group therapy, therapists will be available for support. Some of the research questions ask about sensitive areas such as symptoms and life. We will support participants so that they feel as comfortable as they can, and the meeting can be stopped at any time needed. Participants are not obliged to answer a question if they do not wish to.

Where is the study run from?
Unit for Social and Community Psychiatry, Newham Centre for Mental Health, East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to October2024

Who is funding the study?
The National Institute for Health Research, Health Technology Assessment programme (UK)

Who is the main contact?
Dr Catherine Carr
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Study website
www.elft.nhs.uk/era

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
252526

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 252526, NIHR/HTA 17/29/01

Study information

Scientific Title
Effectiveness of group arts therapy compared to group counselling for diagnostically heterogeneous psychiatric community patients: RAndomised controlled trial in mental health services

Acronym
ERA

Study objectives
For patients with a clear preference for a single arts modality, the addition of arts within therapeutic groups will reduce symptom distress to a greater degree than wider non-specific group effects (as seen in talking therapies such as group counselling) alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/12/2018, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (Mercure Doncaster Centre Danum, High Street, Doncaster, DN1 1DN; 0207 104 8091, 0207 104 8079; nrescommittee.yorkandhumber-southyorks@nhs.net), ref: 18/YH/0464

Study design
Interventional pragmatic multi-centre two-arm randomized controlled trial with internal pilot, economic evaluation and nested process evaluation

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Psychological distress in people with schizophrenia and related psychotic disorders, mood disorders and anxiety or other non-psychotic disorders

Interventions
Participants will be randomly allocated with equal chance to receive either their preferred form of group arts therapy (art, dance movement or music therapy), or group counselling. Participants will choose the modality of arts therapy that they prefer prior to randomisation. Randomisation will be conducted independently by the Pragmatic Clinical Trials Unit. Researchers conducting assessments will be blind to the intervention.
All groups (arts therapy and counselling) will run for up to 90 minutes, twice per week for 20 weeks.
Follow-up assessments will be taken immediately at the end of 20 weeks of treatment, 6 months and 12 months post-treatment.

Intervention Type
Other

Primary outcome measure
Psychological distress, assessed using the Brief Symptom Inventory Global Severity Index, at the end of 20 weeks of treatment

Secondary outcome measures
The following are assessed at the end of 20 weeks of treatment, and 6 and 12 months post-treatment:
1. Psychological distress, assessed using the Brief Symptom Inventory (all subscales)
2. Observer-rated psychiatric symptoms, assessed using the Brief Psychiatric Rating Scale (BPRS)
3. Quality of life, assessed using the Manchester Short Assessment of Quality of Life (MANSA)
4. Objective social situation, assessed using the Objective Social Outcomes Index (SIX)
5. Use of health and social care, assessed using the Client Services Receipt Inventory (CSRI)
6. Self-related health to estimate Quality-adjusted life years (QALYS), assessed using the EQ-5D-3L questionnaire

Overall study start date
01/09/2018

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Outpatient in secondary mental health care
2. Motivation to attend group arts therapy for 5 months and expression of preference for one of three forms
3. Aged 18 years or older
4. Primary diagnosis of ICD-10 - diagnosed with at least one of the following (participants are not required to be diagnosed with all three):
4.1. F2 (schizophrenia and related psychotic disorders)
4.2. F3 (mood disorders)

4.3. F4 (anxiety and other non-psychotic disorders)
5. Duration of current mental disorder of 6 months or longer
6. At least moderate symptom level on BSI (score of 1.65 or above on Global Severity Index)
7. Capacity to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
420

Total final enrolment
425

Key exclusion criteria
1. Primary diagnosis of organic mental disorder (F0), substance misuse (F1), personality disorder (F6)
2. Duration of current mental disorder <6 months (i.e. patients with short-term crises)
3. Physical condition that prevents attendance of group arts therapies
4. Insufficient command of English for communication with other group members and therapists.

Date of first enrolment
01/02/2019

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East London NHS Foundation Trust
Unit for Social and Community Psychiatry,
Newham Centre for Mental Health
Glen Road
London

United Kingdom
E13 8SP

Study participating centre
Avon and Wiltshire Partnership NHS Trust
Research & Development Office
Blackberry Hill Hospital
Bristol
United Kingdom
BS16 2EW

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
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London
United Kingdom
NW1 3AX

Sponsor information

Organisation
East London NHS Foundation Trust

Sponsor details
Noclor
1st Floor, Bloomsbury Building, St Pancras Hospital
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United Kingdom

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+44 (0)203 3173045
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

Website
www.noclor.nhs.net

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Not defined

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
A final report will be prepared for publication via the open access NIHR HTA journal. Further publications will be submitted to peer-reviewed journals. Lay summaries will be made available via the study website and we will run workshops on the study interventions and findings.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan

For data sharing please contact: Dr Catherine Carr - c.e.carr@qmul.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v5.0	26/02/2020	04/12/2020	No	No
HRA research summary			28/06/2023	No	No
Protocol article		26/08/2023	29/08/2023	Yes	No
Protocol file	version 8	30/10/2022	05/04/2024	No	No