

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

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
30/08/2018	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
12/09/2018	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
22/11/2024	Mental and Behavioural Disorders	<input type="checkbox"/> 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 October 2024

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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## Contact information

Type(s)

Public

Contact name

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## Additional identifiers

Integrated Research Application System (IRAS)

252526

Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

## **Total final enrolment**

### **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**

United Kingdom

England

### **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  
Regents PLACE  
London  
United Kingdom  
NW1 3AX

## Sponsor information

**Organisation**  
East London NHS Foundation Trust

**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

## 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?
<a href="#">Protocol article</a>		26/08/2023	29/08/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version v5.0	26/02/2020	04/12/2020	No	No
<a href="#">Protocol file</a>	version 8	30/10/2022	05/04/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes