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Secure care hospital evaluation of art therapy

Submission date 16/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/01/2023	**Overall study status** Completed	
Last Edited 25/11/2025	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
In the past people who have a learning disability were often excluded from taking part in research. This means that knowing what works well for them is not always clear. Lots of psychotherapies available to help people with mental health difficulties are based on talking, which might not always be the best approach for people with learning disabilities/difficulties. Doing artwork or creative things within art psychotherapy can be a helpful way for people to communicate about themselves. Interpersonal art psychotherapy has been designed to help people with learning disabilities in secure care. The art psychotherapist encourages people to use creative ways to express the things they would like to feel better about.
We want to find out if interpersonal art psychotherapy is helpful and value for money for people with learning difficulties who are in secure care. We will be testing if interpersonal art psychotherapy works better than the standard care that is being provided.

Who can participate?
Patients aged 18 to 60 years, with a Learning Disability Screening Questionnaire (LSDQ) score of 57 or below (indicating the presence of learning disability/borderline intellectual functioning /learning difficulty).

What does the study involve?
During the study a computer will decide which people in the research get art therapy straight away and which people wait a bit longer. All participants will be asked to complete some questionnaires about your mental and physical health. You will be asked questions at the start, after four months, and after nine months.

What are the possible benefits and risks of participating?
Art therapy may help participants to feel better. Participants will have to give up some of their free time to take part and Sometimes people can feel emotional during and after art therapy, but your art therapist or staff will help you with this

Where is the study run from?
Cumbria Northumberland Tyne and Wear NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2022 to August 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Paula Foscarini-Craggs, Schema@cardiff.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Paula Foscarini-Craggs

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
319325

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54895, NIHR301264

Study information

Scientific Title
Secure Care Hospital Evaluation of Manualised (interpersonal) Art-psychotherapy: a randomised controlled trial

Acronym
SCHEMA

Study objectives
Is interpersonal art therapy effective at reducing the frequency and severity of aggressive behaviour in adult secure care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2023, London - City & East Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 1048134; cityandeast.rec@hra.nhs.uk), ref: 23/LO/0026

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Learning disorders

Interventions
Participants will be randomised on a one-to-one basis to receive either interpersonal art therapy or be placed on a wait list to receive interpersonal art therapy after they complete their trial participation. Randomisation will be stratified by diagnosis of psychosis and sex.

The interpersonal art therapy comprises 12 sessions with up to 3 additional sessions (a total of 15 possible sessions) which look at personal goals, coping and self-managed, life events and imagined futures. Therapy sessions will be audio recorded. The recordings will be analysed as part of the assessment of the therapeutic process. An assessment of the frequency and severity of aggressive behaviours will be completed weekly after the completion of therapy up to 38 weeks post-randomisation. During the trial, participants will complete two assessments of the quality of life, and a measure of distress associated with psychiatric symptoms at 19 and 38 weeks post-randomisation. At 19 weeks and 38 weeks post-randomisations, healthcare staff will complete proxy measures of the participant's quality of life, and healthcare resource use. After the 38 week follow-up has been completed, participants will be offered the opportunity to participate in the interpersonal art therapy.

A subset of participants will also be asked if they want to take part in an interview to assess their experiences of taking part in interpersonal art therapy. Interviews will last approximately 1 hour. Therapists will also be asked to take part in interviews to assess their experience of providing therapy and its implications for clinical practice.

Intervention Type
Behavioural

Primary outcome(s)

Aggressive behaviour is measured using the Modified Overt Aggression Scale (MOAS) at week 19, weekly between week 19-38, and week 38

Key secondary outcome(s))
1. Health Economic analysis will be measured using the EQ5D, the Recovery Quality of Life Scale, and a resource use questionnaire, at baseline, week 19, and week 38
2. Patient distress attributed to psychiatric symptoms is measured using the brief symptom inventory and is measure at week 19 and week 38

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/02/2024:
1. An inpatient in an NHS secure hospital/unit/service with the presence of learning disability /borderline intellectual functioning indicated by either (a) meeting validated assessment criteria (recognised cognitive testing and adapting functioning assessment), or (b) a score of 57 or below on the Learning Disability Screening Questionnaire (LDSQ)
2. Age 18 to 60 years
3. Able to give informed consent
4. A HONOS (Health of the Nation Outcome Scale) score between 1 and 4 for item 1 (Overactive, aggressive, disruptive, or agitated behaviour / Behavioural problems directed at others)
5. The participants' involvement in the study is supported by their responsible clinician and/or multidisciplinary team (MDT)

Previous inclusion criteria:
1. An inpatient in an NHS secure hospital/unit/service with a Learning Disability Screening Questionnaire (LSDQ) score of 57 or below (indicating the presence of learning disability /borderline intellectual functioning/learning difficulty)
2. Age 18 to 60 years (within the age range for the service)
3. Able to give informed consent
4. A score between 1 and 4 on question 1 of the Health of the Nation Outcome Scale Working Age Adult or Learning Disability version (HONOS-WAA or HONOS-LD)
5. The patient’s involvement in the study is supported by their responsible clinician and/or multidisciplinary team (MDT)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
50

Key exclusion criteria
Current exclusion criteria as of 28/02/2024:
1. Unable to give informed consent
2. Learning disability/borderline intellectual functioning not indicated based on a validated assessment or screening questionnaire (i.e. not meeting validated assessment criteria or a LDSQ Score >57)
3. A HONOS score of 0 for item 1
4. Planned discharge within 12 months of the start of the study
5. Unstable/unmanaged psychotic symptoms requiring active assessment or treatment including medication dose titration (i.e., dose adjustment in the previous 4 weeks or with potential further dose adjustment planned for the following 4 weeks)

Previous exclusion criteria:
1. LDSQ Screening score >57
2. Unable to give informed consent
3. A score of 0 on question 1 of the HONOS-WAA or HONOS-LD
4. Planned discharge within 12 months of the start of the study
5. Receiving active assessment or treatment for acute or unstable/unmanaged psychotic symptoms including medication dose titration

Date of first enrolment
01/02/2023

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth

Newcastle upon Tyne
England
NE3 3XT

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
England
E1 8DE

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1
50 Summer Hill Road
Birmingham
England
B1 3RB

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
England
BA1 3QE

Study participating centre
West London NHS Trust
1 Armstrong Way
Southall
England
UB2 4SD

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham

England
NG3 6AA

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre
Kneesworth House Hospital
Kneesworth House
Old North Road
Bassingbourn
Royston
England
SG8 5JP

Sponsor information

Organisation
Cumbria Northumberland Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Funder Name
National Institute for Health and Care 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
The data set will be available upon request by emailing Dr Paula Foscarini-Craggs (schema@Cardiff.ac.uk) at the end of the trial. While there are no specific criteria, any data requests will be reviewed in accordance with the Centre for Trials Research data sharing policy and procedures.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/03/2025	17/04/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.3	13/01/2023	18/01/2023	No	Yes
Participant information sheet	Pictorial PIS version 1.2	13/01/2023	18/01/2023	No	Yes
Participant information sheet	Therapist information sheet version 1.2	13/01/2023	18/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.3	22/11/2022	18/01/2023	No	No
Statistical Analysis Plan		01/07/2025	02/07/2025	No	No