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Art therapy for people with learning disabilities in secure care

Submission date
01/06/2020

Recruitment status
No longer recruiting

Registration date
09/06/2020

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Art therapy is a treatment that is available to people in the hospital. It involves making some artwork and talking to a therapist. You don't have to be good at art or interested in art to do well in art therapy. People make pictures in art therapy that can help start a conversation with the therapist. Researchers think that art therapy can be helpful for people who have a learning disability. Art therapy has helped some people in some secure care hospitals to be less aggressive. The aim of this study is to find out if we can run a trial of art therapy for people with learning disabilites in secure care. This means the researchers will be testing out on a smaller scale if people want to take part in the study before they go on to do a bigger study.

Who can participate?
Patients in an NHS secure care hospital who have a learning disability

What does the study involve?
About half of the participants will start to work with an art therapist straight away and have 15 art therapy sessions and the other half will wait 4 months before they have art therapy. Everybody who chooses to take part in this research will get art therapy eventually. A member of the research team will ask participants questions at the start, after 4 months, and again at about 6 months.

What are the possible benefits and risks of participating?
Working with the art therapist might help participants feel a bit more settled. However, there is a possibility that the therapy might not help them.

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

When is the study starting and how long is it expected to run for?
April 2014 to June 2019

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

Who is the main contact?
Dr Simon Hackett
simon.hackett@newcastle.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Simon Hackett

ORCID ID
https://orcid.org/0000-0002-7861-5991

Contact details
Newcastle University
Population Health Sciences Institute
Baddiley-Clark Building
Newcastle upon Tyne
United Kingdom
NE2 4AX
+44 (0)191 222 7045
simon.hackett@newcastle.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
191223

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 191223

Study information

Scientific Title
Interpersonal art psychotherapy for the treatment of aggression in people with learning disabilities in secure care: a feasibility study and acceptability study

Acronym
IAP-A

Study objectives

To assess the feasibility and acceptability of carrying out a randomized controlled trial of art psychotherapy for treatment or aggression in people with learning disabilities in secure care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/08/2016, North East - Newcastle & North Tyneside 2 Research Ethics Committee (REC Office Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow Tyne & Wear, NE32 3DT, UK; +44 (0)207 104 8118; newcastlenorthtyneside2.rec@hra.nhs.uk), REC ref: 16/NE/0220

Study design
Multi-site individually randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aggression in patients with learning disabilities in secure care

Interventions
Participants are randomised to either interpersonal art psychotherapy treatment plus usual care or usual care with delayed treatment (waiting-list). Simple randomisation is used to generate the allocation sequence. The concealed sequence is retained by a research assistant who is independent from the recruitment process at each study site. Following the consent procedures, allocation concealment is in place for each therapist facilitating participant enrolment. After the first assessment point the study therapists request the allocation via email contact with the research assistant on a participant by participant basis. Participants are then informed if they had been assigned to either interpersonal art psychotherapy or to usual care delayed treatment.

Treatment arm
Interpersonal art psychotherapy consisted of 15 individual 1-hour sessions completed within 18 weeks. The therapy topic session schedule is as follows, sessions 1 to 3 personal goals, coping responses and self-management; 4 to 5 relationships; 6 to 10 life events; 11 to 12 interpersonal themes; 13 to 15 imagined future and final review. The structure of each therapy session is as follows: the therapist introduces the session content, joint agenda setting, a directed art activity (as determined by the manual and session schedule), a reflective discussion about the art activity. Therapists ‘augment’ reflective discussions by using or creating additional visual material to aid communication and understanding. The study therapists are all registered with the UK Health and Care Professions Council (HCPC) as art psychotherapists with experience of working in secure care with people who have learning disabilities. Study therapists complete 2 days of training included familiarization with the manual, formal teaching, group discussion, and rehearsal/role-play. During the study individual clinical supervision is provided on a fortnightly to monthly basis.

Assessment & follow-up
Treatment carried out (15 sessions) within 18 weeks
Assessment at baseline/pre-, post-, and follow-up at 12-week post-treatment (week 30).

Comparator
Usual Care (delayed treatment/waiting-list)
Usual care within inpatient secure settings involves assessment and treatment by a specialist multi-disciplinary team (MDT) using the Care Programme Approach (CPA) to coordinate and plan care. MDTs are comprised of psychiatrists, clinical and forensic psychologists, mental health and intellectual disability nursing staff, and Allied Health Professionals (AHPs), for example, occupational therapists, arts therapists, and speech and language therapists. The work of MDTs includes risk assessment/formulation and management, recovery-focused care and/or positive behaviour support (PBS). Access to psychotherapy/psycho-educational work includes anger management and anger maintenance, emotions group, drug and alcohol work, speech and language therapy and/or communication group, art therapy group, relaxation, sex education and specific offence related treatment, such as sex offender treatment. Pharmacotherapy treatment and review include (where required) the prescription of mood stabilisers, antipsychotic medication, stimulant medication (for the treatment of Attention Deficit Hyperactivity Disorder), and rapid tranquilising medication, as required (PRN).

Assessment & follow-up
Usual care delayed treatment/waiting-list for 18 weeks
Assessment at baseline/pre-, post-(at 18 weeks), prior to commencement of delayed treatment.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility assessed by:
1. Recruitment and consent, such as patients' willingness to be randomised and clinicians willingness to recruit their patients into the study; assessed by the recruitment target being met for the number of consented participants at enrolment (n=20)
2. Identifying issues related to seeking informed consent and risks of coercion, including potential for patients to participate in the study believing it will positively or negatively influence their inpatient treatment or detention under the mental health act; assessed during enrolment from the number of patients agreeing and/or declining to participate and the responses collected from patients declining to participate after receiving study participant information.
3. Procedures and materials, including suitability of study information, suitability of outcome measures, appraising burden of outcome measures and validated tools and suitability of outcome data collection procedures for maintaining data integrity from multiple study sites; assessed by local research assistants reporting feedback from patients at each data collection point (baseline, post- (18 weeks), follow-up (30 weeks)) on the burden of outcome questionnaires. The level of completion of questionnaires (instrument and item response rates) will be monitored and recorded within routine data integrity checks.
4. Describing routine care/treatment as usual, identifying characteristics of treatment as usual across multiple sites, levels of high and medium/low security, and individualised patient care pathways; assessed via an inventory of participant care plans found within medical records conducted by research assistants for all enrolled participants across multiple-sites at baseline.
5. Attrition and acceptability, including rates of attendance for treatment, reasons for non-attendance and/or drop-out, and lack of retention for data collection at the follow-up points; assessed by study therapists recording participant attendance/non-attendance to treatment sessions, research assistants recording participant reasons for drop-out (including those in the delayed treatment wait-list arm), and rates of retention for follow-up data collection.
6. Identifying risks of contamination, such as patients on the waiting-list/delayed treatment arm

receiving active components of the treatment during routine care; assessed at baseline by completion of an inventory of participant care plans carried out by research assistants for all enrolled participants across multiple-sites with an ongoing review of care provision for participants in the treatment arm completed by study therapists up to 18 weeks.
7. Treatment fidelity, identifying therapist adherence with the required activity in the treatment manual and piloting treatment fidelity; as assessed by measures of inter-rater reliability applied within treatment fidelity checks, random selection and treatment fidelity checklist assessment of audio recordings of treatment sessions (n=27 session recordings), and post-study qualitative group interviews with all study therapists to capture their responses to delivering the manualised intervention.

Key secondary outcome(s))
1. Aggression measured using the Modified Overt Aggression Scale (MOAS) – observational, collected by research assistant weekly for 30 weeks
2. Psychiatric/mental health symptoms measured using the Brief Symptom Inventory (BSI), administered by a research assistant at baseline/pre-, post- (18 weeks), and follow-up (week 30)
3. Anger measured using the Novaco Anger Scale (NAS) administered by a research assistant at baseline/pre-, post- (18 weeks), and follow-up (week 30)
4. Anxiety measured using the Glasgow Anxiety Scale for people with intellectual disability (GAS-ID) administered by a research assistant at baseline/pre-, post- (18 weeks), and follow-up (week 30)
5. Quality of life - capability measured using the ICEpop CAPability Quality of Life measure for Adults (ICECAP-A V2) administered by a research assistant at baseline/pre-, post- (18 weeks), and follow-up (week 30)
6. Therapeutic alliance measured using the Working Alliance Inventory (WAI-Therapist) completed by study therapists at the first therapy session and at 3-week intervals following the start of treatment for 18 weeks

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Adult between the age of 18 to 60 years
2. An inpatient in a NHS secure hospital, with an IQ of between 55 and 79 (within a range including moderate, mild, and borderline intellectual functioning)
3. Able to give informed consent
4. Having a clinical profile, as assessed by the local clinical team, as requiring psychotherapy

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
20

Key exclusion criteria
1. Unable to give informed consent
2. Having no clinical indicators for the psychotherapeutic treatment in their clinical profile
3. Had a planned discharge from hospital within 12 months of the start of the study
4. Were undergoing medication dose titration for the treatment of acute psychotic symptoms

Date of first enrolment
01/02/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Cumbria Northumberland Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

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

Individual participant data (IPD) sharing plan
Due to this being a feasibility study the primary outcomes, feasibility objectives will be reported in the publication arising from the study. Outcome measure datasets for this study are small and will not be made available. Datasets will be retained at Newcastle University. Summary statistics will be presented within the publication arising from the study for each outcome measure separately by arm at each study time point (baseline and post-test). Summary statistics for the difference between post-test and baseline timepoints will also be presented within each trial arm.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	16/12/2020	Yes	No
Protocol article	protocol	10/10/2017	01/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes