

Controlled randomised evaluation of group art therapy

Submission date 20/03/2009	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/03/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/03/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 3.0 27/01/2009

Study information

Scientific Title

Controlled Randomised Evaluation of group Art Therapy for people with personality disorder

Acronym

CREATe

Study objectives

Among people with personality disorder, those randomised to referral for arts therapies plus treatment as usual will have improved mental health, as measured by the Clinical Outcome in Routine Evaluation (CORE) at 30 months, compared to those receiving treatment as usual alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ealing and West London Research Ethics Committee, 02/03/2009, ref: 08/H0710/86

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Personality disorder

Interventions

Weekly group art psychotherapy for up to 24 months versus treatment as usual.

Treatment as usual will conform to standards laid down in draft national guidance on the management of people with borderline personality disorder (National Institute for Clinical

Excellence 2008) and be based on regular out-patient review. This will take place at least once every three months. Other elements of treatment as usual will vary depending on patient needs but in all cases it will include; consideration of psychotropic medication, and the option of referral to crisis team and inpatient psychiatric treatment.

The total duration of follow-up is 30 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Clinical Outcomes Routine Evaluation at 30 months

Secondary outcome measures

1. Mental health measured using the CORE at 6 and 18 months
2. Social functioning measures using the Social Functioning Questionnaire at 6, 18 and 30 months
3. Satisfaction with care using the 8-item Client Satisfaction Questionnaire at 6, 18 and 30 months
4. Quality of life using Euro-Qol at 6, 18 and 30 months
5. Frequency of suicidal acts and acts of deliberate self harm collected via a self-report questionnaire developed specifically for the study and measured at 6, 18 and 30 months
6. Direct costs (healthcare and non-health care) and productivity costs will be calculated for at 18 and 30 months. Service utilisation data will be collected via a self-report questionnaire developed specifically for the study
7. Global Assessment of Functioning, a 100-point single item, observer-rated scale that rates functioning on a continuum from health to illness rated at 6, 18 and 30 months

Overall study start date

01/04/2009

Completion date

30/09/2013

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Either sex, aged 18 to 70 years
2. Living in the London Boroughs of Kensington and Chelsea or Westminster
3. Have a primary diagnosis of personality disorder (PD)
4. Referred to the Waterview Centre
5. Have a diagnosis of PD confirmed using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (SCID-II)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

1. A primary diagnosis of a psychotic disorder, alcohol or drug dependence (those with a history of transient psychotic symptoms and non-dependent substance misuse will be included)
2. Already in receipt of art, music or another arts therapy
3. Currently being treated on a compulsory basis (under the Mental Health Act)
4. Unwilling to provide written informed consent to participate in the trial

Date of first enrolment

01/04/2009

Date of final enrolment

30/09/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Imperial College London

London

United Kingdom

W6 8LN

Sponsor information

Organisation

Imperial College London

Sponsor details

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Sponsor type

University/education

Website

<http://www3.imperial.ac.uk/>

ROR

<https://ror.org/041kmwe10>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Central and North West London NHS Foundation Trust

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration