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Controlled randomised evaluation of group art therapy

Submission date	Recruitment status	[X] Prospectively registered
20/03/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/03/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/03/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mike Crawford

ORCID ID
https://orcid.org/0000-0003-3137-5772

Contact details
Department of Psychological Medicine
Imperial College London
Claybrook Centre
37 Claybrook Road
London
United Kingdom
W6 8LN
+44 (0)20 7386 1231
m.crawford@imperial.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Clinical Outcomes Routine Evaluation at 30 months

Key secondary outcome(s)
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 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
Imperial College London
London
United Kingdom
W6 8LN

Sponsor information

Organisation
Imperial College London

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration