

Therapeutic community intervention trial

Submission date 24/08/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/11/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2.0

Study information

Scientific Title

An exploratory randomised trial of day-therapeutic community treatment for people with personality disorder

Acronym

TACIT

Study objectives

Among people with personality disorder, those randomised to referral for treatment from a day-based Democratic Therapeutic Community will have fewer days of psychiatric inpatient treatment at one year, compared to those receiving treatment as usual supplemented by the construction of a Crisis Plan.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford Ethics Committee (REC B), 15/01/2009, ref: 08/H0605/87

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

Patient information can be found at <http://www.psox.org/ocns/Information%20sheet.pdf>

Health condition(s) or problem(s) studied

Personality disorder

Interventions

Democratic Therapeutic Communities (DTC) is a form of psychosocial treatment based on a collaborative and deinstitutionalised approach to staff-patient interaction; particular emphasis is placed on personal responsibility, sharing and participation in communal activity.

The four day Democratic Therapeutic Communities taking part in this study are all members of the Association of Therapeutic Communities and are all well established. They all offer day-patient and outreach services.

The control condition will be delivered by members of a local Complex Needs team, and will consist of the construction of a crisis plan identifying triggers for deterioration in mental state, and practical steps that can be taken to get support or to maintain stability. This plan will be

reviewed at 6, 12 and 24 months. Other elements of control treatment vary depending on patient needs and local service organisation but in all cases it includes outpatient monitoring, consideration of psychotropic medication and the option of referral to outpatient psychotherapy treatment and inpatient psychiatric treatment at times of crisis; these elements will be delivered by local general practitioners or Community Mental Health Teams.

Intervention Type

Behavioural

Primary outcome measure

Number of days of inpatient psychiatric treatment in the year following randomisation.

Secondary outcome measures

1. Mental health - assessed using the General Health Questionnaire
2. Social Functioning - assessed using the Social Function Questionnaire
3. Extent of any aggressive behaviour towards others using the Modified Overt Aggression Scale
4. Satisfaction with care using the 8-item Client Satisfaction Questionnaire
5. Quality of life using Euro-Qol
6. Frequency of suicidal acts and acts of deliberate self harm collected via a self-report questionnaire developed specifically for the study
7. Direct costs (healthcare and non-health care) and productivity costs using a self-report questionnaire developed specifically for the study
8. Symptoms of personality disorder, and whether participants continue to fulfil criteria, will be assessed by repeat administration of the Structured Clinical Interview for DSM IV Axis II Personality Disorders.

Overall study start date

01/07/2009

Completion date

30/06/2013

Eligibility

Key inclusion criteria

The study sample will be recruited from people in contact with primary care or mental health services and living in Oxfordshire. Day-Therapeutic Community services in this area are provided at four communities (in Oxford, Banbury, Wallingford and Witney). The study sample will be:

1. Resident in the community
2. Aged between 16 and 65
3. Have a diagnosis of personality disorder (assessed using the Structured Clinical Interview (II) for Axis 2 disorder)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

85

Total final enrolment

70

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. A degree of learning disability, or intellectual impairment which prevents engagement in Therapeutic Community services
3. Unwilling to provide written informed consent to participate in the trial

Date of first enrolment

01/07/2009

Date of final enrolment

30/06/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Oxfordshire Complex Needs Service

Oxford

United Kingdom

OX4 1XE

Sponsor information

Organisation

Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust (UK)

Sponsor details

Trust Headquarters

4000 John Smith Drive

Oxford Business Park South

Oxford

England

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04c8bjx39>

Funder(s)

Funder type

Government

Funder Name

Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2017		Yes	No