# Therapeutic community intervention trial

Submission date Prospectively registered Recruitment status 24/08/2009 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 18/02/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category 02/11/2022 Mental and Behavioural Disorders

#### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Dr Steve Pearce

#### Contact details

Oxfordshire Complex Needs Service Manzil Way Oxford United Kingdom OX4 1XE

## Additional identifiers

#### Protocol serial number

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

### Study type(s)

**Treatment** 

### 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(s)

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

### Key secondary outcome(s))

- 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.

#### 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

### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

**United Kingdom** 

England

Study participating centre
Oxfordshire Complex Needs Service
Oxford
United Kingdom
OX4 1XE

# Sponsor information

### Organisation

Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust (UK)

#### **ROR**

https://ror.org/04c8bjx39

# Funder(s)

### Funder type

Government

#### **Funder Name**

Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust (UK)

### **Results and Publications**

### 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
Results article

**Details** 

Date created Date added Peer reviewed? Patient-facing?

01/02/2017 Yes