

# Psychological treatments for severe and complex mental health problems/personality disorder. A phase II randomised controlled trial

<b>Submission date</b> 26/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/03/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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## Additional identifiers

**Protocol serial number**  
ZC56

## Study information

**Scientific Title**

Psychological treatments for severe and complex mental health problems/personality disorder.  
A phase II randomised controlled trial

**Acronym**

SPeDi (Sheffield Personality Disorders)

**Study objectives**

For patients with Cluster B personality disorders (as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV], Axis II), enhanced community mental health team (CMHT) management plus a cognitively-based psychotherapy is a more effective treatment than routine CMHT management alone. (The psychotherapies being used are Cognitive Analytic Therapy [CAT] and Cognitive Behavioural Therapy [CBT].)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

North Sheffield Ethics Office, 17/01/05, ref: 04/Q2308/80

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Personality disorders

**Interventions**

CMHT management alone versus CMHT management plus cognitively-based psychotherapy.

**Intervention Type**

Other

**Phase**

Phase II

**Primary outcome(s)**

The Risk subscale of the CORE tool (Clinical Outcomes in Routine Evaluation)

**Key secondary outcome(s)**

Health Status Questionnaire (SF36), Borderline Personality Disorder Checklist (BPD-CL), incidents of self-harm (Acts of Deliberate Self-Harm Inventory, ADShI), economic cost of service use.

**Completion date**

31/10/2007

## Eligibility

### Key inclusion criteria

1. Adult out-patients (18-65) of community mental health teams (CMHTs)
2. Minimum one year history of severe, complex mental health problems, diagnosis of at least one Cluster B personality disorder

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Upper age limit

65 years

### Sex

All

### Key exclusion criteria

Current in-patient, actively psychotic, primary drug/alcohol abuse.

### Date of first enrolment

01/05/2005

### Date of final enrolment

31/10/2007

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**Mental Health Section**

Sheffield

United Kingdom

S1 4DA

# Sponsor information

## Organisation

Sheffield Health and Social Research Consortium (UK)

## Funder(s)

### Funder type

University/education

### Funder Name

University of Sheffield, Sheffield Health and Social Research Consortium (ref ZC56) (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration