

# 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

### 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

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

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.

**Overall study start date**

01/05/2005

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

220

**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**

England

United Kingdom

### **Study participating centre**

#### **Mental Health Section**

Sheffield

United Kingdom

S1 4DA

## **Sponsor information**

### **Organisation**

Sheffield Health and Social Research Consortium (UK)

### **Sponsor details**

Fulwood House

Old Fulwood Road

Sheffield

United Kingdom

S10 3TH

### **Sponsor type**

Government

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

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

## **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