

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

Submission date 26/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 29/07/2005	Overall study status Completed	☐ Protocol
Last Edited 15/03/2017	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Glenys Parry

Contact details

Mental Health Section
The School of Health and Related Research (ScHARR)
University of Sheffield
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 2220817
G.D.Parry@sheffield.ac.uk

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

Primary study design

Interventional

Study design

Randomised controlled trial

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