Evaluation of a cognitive-behavioural (schemafocused) therapy in the personality disorder service at Ashworth Hospital

Recruitment status No longer recruiting	Prospectively registered		
	Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Montal and Robaviousal Disorders	Individual participant data		
	No longer recruiting Overall study status Completed		

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

Protocol serial number RDS/03/152

Study information

Scientific Title

Acronym

Schema Modal Therapy Trial

Study objectives

- 1. That the enhanced Cognitive-Behavioural Therapy (CBT) intervention with a focus on personal schema will result in a statistically significant improvement in scores on dynamic measures of risk and cognitive, affective and behavioural dispositions of relevance to antisocial behaviour (Antisocial Personality Questionnaire [APQ]) on an individual and group basis compared with 'Treatment As Usual' (TAU) models of care
- 2. That a Schema-Focused (SF) approach will result in lower rates of attrition from therapy due to the nature of this work, than TAU approaches
- 3. That observed improvements in levels of functioning will be maintained at six and 12 months follow-up within the institution

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Liverpool (Adult) Local Research Ethics Committee on the 28th April 2004 (ref: 04/02/324/A).

Study design

Independent phase II Medical Research Council (MRC) framework exploratory trial using a randomised controlled trial methodology

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Personality Disorder

Interventions

Subjects will be randomly assigned to the 'Treatment As Usual' (TAU) group versus the enhanced CBT group (TAU or SF-CBT). Randomisation will take place in such a way that each of the clinical teams managing cases will have an equal number of cases in the TAU and SF-CBT groups. Randomisation will be conducted, independently, by a remote telephone randomisation service.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

Personal schemata

Key secondary outcome(s))

- 1. Personality traits
- 2. Risk to others
- 3. Interpersonal style
- 4. Emotional regulation
- 5. Impulsiveness

Completion date

01/10/2009

Eligibility

Key inclusion criteria

- 1. Male personality disorder patients
- 2. Aged between 18 and 70 years
- 3. Currently a resident at Ashworth Hospital; new admissions will also be included in the study if they are allocated to stay for the duration of the treatment intervention

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

Male

Key exclusion criteria

- 1. Current psychotic symptoms
- 2. Organic brain syndromes
- 3. Intelligence Quotient (IQ) less than 70

Date of first enrolment

01/11/2004

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

United Kingdom

Study participating centre Edenfield Centre Manchester United Kingdom

M25 3BL

Sponsor information

Organisation

University of Manchester (UK)

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Government

Funder Name

Dangerous & Severe Personality Disorder (DSPD) Programme, Home Office (UK) (ref: RDS/03/152)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	results	01/03/2010		No	No