

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

<b>Submission date</b> 01/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/09/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Personal schemata

**Secondary outcome measures**

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

**Overall study start date**

01/11/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Male

**Target number of participants**

60

**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**

England

United Kingdom

**Study participating centre**

**Edenfield Centre**

Manchester

United Kingdom

M25 3BL

**Sponsor information****Organisation**

University of Manchester (UK)

**Sponsor details**

Research Contracts Office

Oxford Road

Manchester

England

United Kingdom

M13 9PL

jane.wells@manchester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.manchester.ac.uk/>

ROR

## Funder(s)

### Funder type

Government

### Funder Name

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

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Funder report results</a>	results	01/03/2010		No	No