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

Submission date
01/11/2006

Recruitment status
No longer recruiting

Registration date
13/02/2007

Overall study status
Completed

Last Edited
04/09/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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

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?
Funder report results	results	01/03/2010		No	No