

Pilot study of Cognitive Behaviour Therapy (CBT) versus usual treatment in those with Antisocial Personality Disorder (ASPD) with aggressive behaviour

Submission date 16/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/08/2009	Condition category 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0400922 ID: 71697

Study information

Scientific Title

Acronym

ASCOT

Study objectives

This pilot study has four specific and related aims.

1. Development of treatment
2. Chart treatment as usual
3. Test out standardised measures and different modes of delivery if levels of literacy are found to be poor
4. Determine a preliminary efficacy estimate for CBT in this group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 13/08/2007:

1. Ethics Board for lead site: NHS Greater Glasgow Primary Care Trust (Community and Mental Health), approved on 16/05/2005 (ref: 05/S0701/46)

Other sites:

2. St Mary's Research Ethics Committee, approved on 10/06/2005
3. Ealing and West London Mental Health Trust (WLMHT) Local Research Ethics Committee, approved on 17/11/2005

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

Antisocial Personality Disorder

Interventions

Cognitive behaviour therapy versus usual treatment

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Aggression & offending behaviour

Secondary outcome measures

1. Social functioning
2. Anxiety and depression
3. Anger
4. Cost effectiveness

Overall study start date

13/09/2005

Completion date

12/09/2007

Eligibility

Key inclusion criteria

1. A diagnosis of ASPD with aggressive behaviour
2. Aged 18 or above
3. Affirmation of any item on the Amended MacArthur Community Violence Screening Instrument (MCVSI)* interview (*3 months prior to baseline)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

56 - closed to recruitment - in follow-up

Key exclusion criteria

1. Those who are currently receiving inpatient treatment for a mental state disorder
2. Those currently receiving a systematic psychological therapy
3. Those who have insufficient knowledge of English to enable them to be assessed adequately and to understand the treatment approach

Date of first enrolment

13/09/2005

Date of final enrolment

12/09/2007

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Psychological Medicine

Glasgow

United Kingdom

G12 0XH

Sponsor information

Organisation

Greater Glasgow NHS (UK)

Sponsor details

Research and Development

Gartnavel Royal Hospital

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Sponsor type

Government

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (G0400922)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Results article	results	01/04/2009		Yes	No