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Cognitive behavioural therapy for People with Asperger Syndrome and Anxiety disorders

Submission date
20/02/2012

Recruitment status
No longer recruiting

Registration date
20/02/2012

Overall study status
Completed

Last Edited
22/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study aims to find out whether or not a psychological treatment, cognitive behaviour therapy (CBT), can help people with Asperger Syndrome (AS) and high functioning autism who have problems with anxiety. AS is often described as a form of high-functioning autism. People with anxiety disorders such as social phobia or specific phobias can be described as being afraid of social situations, or particular situations (e.g., lifts) or objects (e.g., spiders), so much so that a person may avoid going out for social activities or work. They usually experience a sense of dread or fear that something terrible may happen, such as being laughed at or being judged negatively, they may also tremble, sweat, and have panic symptoms. These problems may significantly impair their quality of life. There are many studies showing that CBT can help people with anxiety. Many adults with AS have problems with anxiety but there have been no studies which have tried to find out whether or not CBT can help these people. There have been some completed studies with children with AS showing that CBT can help with anxiety. People with AS tend to have special interests, such as collecting large numbers of items, and have difficulties with social situations. They may have problems with understanding what facial expressions and hand gestures mean, and have difficulties with making friends. It is not surprising that studies have found that people with AS have higher levels of anxiety than people without AS. We want to find out whether or not psychological treatments for anxiety can be adapted and used to successfully treat the anxiety experienced by people with AS.

Who can participate?
Patients aged 16 or over with AS or high functioning autism and clinically significant levels of anxiety from the counties of Norfolk, Kent and Hertfordshire.

What does the study involve?
Participants are randomly allocated into one of two groups. One group receives modified individual and group CBT delivered by trained CBT therapists. The other group is put on a waiting list to receive the CBT later. The CBT involves anxiety management techniques and social skills training. Anxiety is assessed before and after the CBT and at the 6-month follow-up.

What are the possible benefits and risks of participating?
The results of this study may help us to improve satisfaction with the NHS for people with

autistic spectrum disorders who have mental health problems, but do not receive treatment. The study will help to determine whether or not CBT will be effective at improving anxiety amongst adults with AS, and whether it represents good value for money.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
August 2011 to August 2012

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8370

Study information

Scientific Title
Cognitive behavioural therapy for People with Asperger Syndrome and Anxiety disorders: a pilot randomised control trial

Acronym
PAsSA

Study objectives
There is a body of literature demonstrating that children, adolescents and adults with Asperger Syndrome (AS) and high functioning autism have signifincant problems with anxiety. There is evidence to suggest that cognitive behaviour therapy (CBT) is an effective treatment for anxiety, and there is a growing interest in examining the utility of cognitive behaviour therapy for people with AS who have mental health problems. Currently, there are no known clinical trials in the United Kingdom of cognitive behaviour therapy for anxiety amongst adults with AS, although there are studies examining this in children. There are known methods of modification to therapy for this client group and it is appropriate to undertake a limited trial with adults with AS in the United Kingdom.

The aim is to determine whether or not modified CBT can successfully reduce the symptoms of anxiety experienced by people with AS, and whether or not this intervention is cost effective. We will make use of a single-blind cross-over trial incorporating pre-, post- and follow-up assessment of anxiety. A mixture of clinican ratings and self-ratings of anxiety will be used. The intervention will be modified individual and group CBT delivered by trained CBT therapists, and the assessment of anxiety will be completed by research assistants who will be blind to group allocation.

This study is a randomised single blind cross over trial of CBT for people with AS who have clinically significant levels of anxiety. Thirty five participants who complete the entire trial will be recruited from the counties of Norfolk, Kent and Hertfordshire. However, we may include other counties in the future. Levels of symptomatology will be measured pre- and post-group and at follow-up by research assistants who will be blind to group allocation. This will generate data regarding the effectiveness of this type of psychological intervention with people who have AS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 4 NHS Research Ethics Committee, 01/07/2010, ref: 10/H0305/42

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Anxiety, Autism spectrum disorders, Not Assigned; Disease: Anxiety, Autism spectrum disorders

Interventions
Group CBT, The treatment package utilises techniques delivered in a group based format. These include cognitive restructuring, anxiety management techniques, systematic desensitization, exposure to feared social situations, and social skills training. Cognitive restructuring refers to the process of learning to identify unhelpful cognitions which may trigger or maintain anxiety and then learning to challenge or replace these cognitions with cognitions that are rational. Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
1. Social Phobia Inventory (Connor et al., 2000)
2. Liebowitz Social Anxiety Scale (Heimberg et al.)
Timepoint(s): Administered on Three Occassions

Measured before the intervention starts, after the intervention is finished, and at six months after the intervention has finished

Secondary outcome measures
1. Resource Use Questionnaire; Timepoint(s): Administered on Three Occassions
2. SF-36 (www.sf-36.org) and EQ-5D (www.euroqol.org) generic health-related quality of life scales.; Timepoint(s): Administered on Three Occassions
3. Social and Emotional Functioning Interview (Informant and Subject Versions; Rutter et al., 1988); Timepoint(s): Administered on Three Occassions
4. Social Interaction Anxiety Scale (Heimberg et al., 1992; Brown et al., 1997), and
5. Fear Questionnaire; Timepoint(s): Administered on Three Occassions

Measured before the intervention starts, after the intervention is finished, and at six months after the intervention has finished

Overall study start date
08/08/2011

Completion date
08/08/2012

Eligibility

Key inclusion criteria
1. Participants must fulfill diagnostic criteria for AS, or high functioning autism (Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)), and have been diagnosed with AS or PDD-NOS by a paediatrican, clinical psychologist or psychiatrist. The features of AS and PDD-NOS include difficulties with social interaction marked by problems with nonverbal behaviour, and peer relationships. They also have problems with social reciprocity, coupled with stereotyped patterns of behaviour and interests that may be repetitive, as well as clinically significant difficulties with occupational and social functioning. People with AS generally do not have language developmental delays or intellectual disabilities. Only participants with a current diagnosis of AS or PDDNOS will be considered for inclusion within the trial. We will make use of the Krug Asperger Disorder Index as an aide to confirming diagnosis.
2. Participants must have clinical significant difficulties with anxiety and fulfill diagnostic criteria for one or more of the following disorders: panic disorder, agoraphobia, social phobia (social anxiety disorder), specific phobias, or generalised anxiety disorder. This will be confirmed through the use of our screening instruments, such as the Hamilton Rating Scale for Anxiety, and an assessment and screening interview.
3. Participants must be aged 16 or over.; Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 35; UK Sample Size: 35

Key exclusion criteria
1. If suffering from post-traumatic stress disorder, or anxiety related to substance misuse. The reason for this exclusion is that people suffering from these disorders may require more specialist intervention as a consequence of the aetiology of these disorders (e.g. trauma and addiction)
2. They have other types of severe mental illness such as psychosis
3. They are currently abusing substances such as alcohol or heroin
4. They have an intellectual disability

Date of first enrolment
08/08/2011

Date of final enrolment
08/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
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Sponsor information

Organisation
Norfolk and Waveney Mental Health NHS FT (UK)

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Sponsor type
Government

ROR
https://ror.org/03400ft78

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

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?
Protocol article	protocol	30/07/2013		Yes	No
Results article	results	13/04/2016		Yes	No