ISRCTN11219568 https://doi.org/10.1186/ISRCTN11219568

Effective Therapy for Anxiety in Young People with Autism Spectrum Disorder

Submission date	Recruitment status
12/05/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
17/07/2014	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

Contact name
Prof Helen McConachie

Contact details
Institute of Health and Society
Newcastle University
Sir James Spence Institute 3rd Floor
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

Protocol serial number
6868

Study information

Scientific Title
Effective therapy for anxiety in young people with autism spectrum disorder: a pilot randomised treatment trial

Acronym
BAT (Beating Anxiety Together)

Study objectives
The main objective is to establish the acceptability, local suitability and likely variability in outcomes of an adapted group cognitive behavioural therapy (CBT) approach for young people with autism spectrum disorder (ASD) and anxiety disorder. Young people are randomly allocated to intervention or to waiting list control. It is hypothesised that there will be a greater reduction in levels of anxiety in the intervention group compared with control, and that a greater proportion will no longer meet criteria for an anxiety disorder after treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire Research Ethics committee approved on the 21/07/2009 (ref: 09/H1310/44)

Primary study design
Interventional

Study design
Single centre randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Anxiety, Autism spectrum disorders; Disease: Anxiety, Autism spectrum disorders

Interventions
Rehearsal pilot trial of a brief group treatment adapted for children with ASD. Cognitive behaviour therapy has been adapted to the cognitive profile of young people with ASD in a 7 session format published as 'Exploring Feelings', developed and evaluated in Australia. The focus of the group is to develop skills in young people to stop the build-up of anxiety which typically takes a remitting/relapsing course. Parallel group sessions for parents train them in skills to support their child.

Follow-up length: 12 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Anxiety disorders measured with the Anxiety Disorders Interview Schedule (baseline and 3 months)

2. Level of anxiety measured with Spence Childrens Anxiety Scale (parent, child) (baseline, 3, 6, 9 and 12 months)

Key secondary outcome(s)
1. Parent management strategies measured by the Child Development Questionnaire - ASD adaptation (baseline and 3 months)
2. Parent anxiety measured by the Depression Anxiety and Stress Scales (baseline and 3 months)
3. Childrens Automatic Thoughts Scale (baseline and 3 months)
4. Childrens Assessment of Participation and Enjoyment (baseline, 3 and 12 months)

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Children aged 9 - 13 years old, boys and girls
2. Diagnosis of autism, ASD or Asperger syndrome
3. Ability in the average range (Full Scale Intelligence Quotient [FSIQ] greater than 70)
4. Sufficient spoken English to take part in assessments
5. Meeting criteria for anxiety disorder (as assessed by research team)
6. Parent/carer and young person willing to attend group CBT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 Years

Upper age limit
13 Years

Sex
All

Key exclusion criteria
Children with severe conduct or attention problems, or oppositional behaviour, because of likely disruption to the group process.

Date of first enrolment
09/10/2009

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Health and Society
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Trust (UK)

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?

Results article	results	01/08/2014	Yes	No