

Effective Therapy for Anxiety in Young People with Autism Spectrum Disorder

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| Submission date 12/05/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 12/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 17/07/2014 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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
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)

Study design

Single centre randomised interventional treatment trial

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 below to request a patient information sheet

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 measure

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)

Secondary outcome measures

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)

Overall study start date

09/10/2009

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/carers and young person willing to attend group CBT

Participant type(s)

Patient

Age group

Child

Lower age limit

9 Years

Upper age limit

13 Years

Sex

Both

Target number of participants

Planned sample size: 36; UK sample size: 36

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**

England

United Kingdom

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)

Sponsor details

St Nicholas Hospital

Jubilee Road

Gosforth

Newcastle Upon Tyne

England

United Kingdom
NE3 3XT
ali.zaatar@ntw.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.ntw.nhs.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

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 | 01/08/2014 | | Yes | No |