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Intolerance of uncertainty in children with autism spectrum disorder: a feasibility trial

Submission date
30/04/2018

Recruitment status
No longer recruiting

Registration date
14/05/2018

Overall study status
Completed

Last Edited
06/07/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anxiety causes difficulties for around 50% of children with autism spectrum disorder (ASD); childhood anxiety is a major risk factor for anxiety in adulthood. Research shows that anxiety can be caused by uncertainty, leading to Intolerance of uncertainty (IU). People who experience IU believe that uncertainty is stressful and upsetting and should be avoided. IU has an important role in the development and maintenance of anxiety and is a barrier to effective anxiety treatment. Despite this, there are no existing therapies that target IU for children with ASD. The aim of this study is to find out whether a parent-based intervention can assist children with ASD to manage uncertain situations more effectively.

Who can participate?
Parents of children aged 6-16 with ASD and anxiety

What does the study involve?
Families are randomly allocated to either receive the uncertainty intervention or attend a parent group. The uncertainty intervention is run by trained NHS therapists. The researchers meet with families individually at the start of the study to gather information about their child's IU and anxiety. Parents receiving the uncertainty intervention attend an eight-week programme alongside other parents. Parents from the intervention groups are asked to identify a target situation that involves uncertainty through which they practise the strategies learned with their child. The researchers meet with the families individually at the end of the programme and a few months later to find out how acceptable and helpful the intervention was.

What are the possible benefits and risks of participating?
People who take part in this study are given an opportunity to contribute to research which will help to improve the understanding of ASD and anxiety. It is thought that the disadvantages or risks of participating in this study are minimal. The questionnaires ask about everyday behaviours so it is not anticipated that this will cause any problems. All travel expenses for attending sessions will be reimbursed. It might be distressing for parents to discuss their child’s feelings and reactions. If this happens, the researchers will be available to support them and to signpost to other local services for help where appropriate.

Where is the study run from?
1. Northumberland, Tyne and Wear NHS Foundation Trust (UK)
2. Northumbria Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to June 2020

Who is funding the study?
Autistica (UK)

Who is the main contact?
Dr Jacqui Rodgers
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38104

Study information

Scientific Title
Addressing intolerance of uncertainty in children with autism spectrum disorder: an intervention feasibility trial

Study objectives
Anxiety causes difficulties for around 50% of children with autism spectrum disorder (ASD); childhood anxiety is a major risk factor for anxiety in adulthood. Research shows that anxiety can be caused by uncertainty, leading to Intolerance of uncertainty (IU). People who experience IU believe that uncertainty is stressful and upsetting and should be avoided. IU has an important role in the development and maintenance of anxiety and is a barrier to effective anxiety treatment. Despite this, there are no existing therapies that target IU for children with ASD. During the therapy development study, clinicians and parents worked together to develop a parent-based intervention to assist children with ASD to manage uncertain situations more effectively. The intervention was delivered to parents of young people with ASD in a small group setting. During eight two-hour sessions parents were given strategies to assist their child with uncertainty in everyday situations. Parents learned to identify when their child was showing anxiety related to uncertainty and to practice strategies to enable them to tolerate uncertainty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Tyne & Wear South Research Ethics Committee, 17/04/2018, ref: 18/NE/0106

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Autism spectrum disorder

Interventions
Sixty parents of children with ASD and anxiety are recruited from NHS services. Randomisation will occur through the online service ‘Sealed Envelope’ (https://www.sealedenvelope.com/). Families will be randomised to the CUES group (intervention group: A) or the Understanding Autism group (enhanced services as usual group: B) and the result recorded. Randomisation will

be blocked (using random permuted blocks) to ensure that the groups are balanced. There is a single password for a trial and anyone with the password may carry out new randomisations for that trial. This will be done by the RA (Jane Goodwin), although the chief investigator (Dr Jacqui Rodgers) will have access for monitoring. The randomisation results will be shown on-screen and emailed to both the administrator of the trial and to the randomiser.

The uncertainty intervention group will be run by trained NHS therapists. The trialists will meet with families individually at the start to gather information about their child's IU and anxiety. Parents receiving the intervention will attend the eight-week programme alongside other parents. Parents from the intervention groups are asked to identify a target situation that involves uncertainty through which they will practise the strategies learned with their child. The trialists will meet with the families individually at the end of the programme and a few months later to find out how acceptable and helpful the intervention was. The follow ups take place immediately post-treatment (or equivalent for Understanding Autism group), at 12 weeks and 26 weeks post-treatment (or equivalent).

Intervention Type
Other

Primary outcome measure
Intolerance of uncertainty is measured using target behaviour rating of target situations at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment

Secondary outcome measures
1. Children's intolerance of uncertainty (parent and child reported) is measured using the Intolerance of Uncertainty Scale (IUS – P &C, Walker, 2009) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
2. Children's anxiety is measured using the Screen for Child Anxiety Related Emotional Disorders (SCARED; Birmaher et al., 1997) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
3. Children's anxiety (parent and child reported) is measured using the Anxiety Scale for Children - ASD (ASC-ASD, Rodgers et al., 2016) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
4. Children's activities and participation are measured using the Children's Assessment of Participation and Enjoyment (CAPE, King et al., 2004) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
5. Parents' self-efficacy is measured using the Parent Self-efficacy scale (Sofronoff & Farbotko, 2002) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
6. Parents' own intolerance of uncertainty is measured using the Intolerance of Uncertainty Scale (IUS-12; Carleton, 2012) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
7. Parents' mental wellbeing is measured using the Depression, Anxiety and Stress Scale (DASS, Lovibond & Lovibond, 1995) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment
8. Treatment expectancy is measured using the Credibility/Expectancy Questionnaire (Devilly & Borkovec, 2000) at baseline, immediately post treatment (or equivalent for Understanding Autism), 12 weeks and 26 weeks post treatment

Overall study start date

03/01/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Parents of autistic children who:
1.1. Are aged 6-16 years
1.2. Experience some anxiety
1.3. Do not have intellectual disability OR have mild to moderate intellectual disability
1.4. Have sufficient language ability to complete appropriate outcome measures (with assistance if required)
2. Parents/carers have sufficient spoken and written English to provide written informed consent, complete assessments and participate in the intervention

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
53

Key exclusion criteria
1. Children who experience severe and complex anxiety disorder
2. Children with severe intellectual disability
3. Children with complex health conditions
4. Parents with significant mental health difficulties

Date of first enrolment
15/05/2018

Date of final enrolment
21/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Complex Neurodevelopmental Disorders Service (CNDS)
Northumberland, Tyne and Wear NHS Foundation Trust
Walkergate Park
Benfield Road
Newcastle
United Kingdom
NE6 4QD

Study participating centre
Child and Adolescent Mental Health service (CAMHS)
Northumbria Healthcare NHS Foundation Trust
Albion Road Clinic
Albion Road
North Shields
United Kingdom
NE29 0HG

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Charity

Funder Name
Autistica; Grant Codes: 7520

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A protocol paper is under preparation and will be available once completed. The trialists plan to publish the results in a high-impact peer reviewed journal.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the small sample size and potentially identifiable nature of the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/06/2019	01/07/2019	Yes	No
Results article		05/07/2022	06/07/2022	Yes	No
HRA research summary			28/06/2023	No	No