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A parent-led intervention for anxiety in autistic children with severe to profound intellectual disability: A development and proof of concept study

Submission date
15/07/2021

Recruitment status
No longer recruiting

Registration date
19/07/2021

Overall study status
Completed

Last Edited
07/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Autism spectrum disorder (ASD), usually called autism, is something a person is born with. Autism means that the way a person thinks about and experiences the world is different to most people.
Anxiety is a feeling of unease, such as worry or fear, that can be mild or severe.
There is a lack of intervention studies for anxiety in autistic children with severe to profound intellectual disabilities (ID) and who speak few or no words, despite anxiety being highly prevalent in this population. The lack of evidence-based interventions is concerning given that mental health difficulties have been identified as a major priority for autistic children and their families (James Lind Alliance Priority Setting Partnership).

We will work with families and clinicians to develop and implement a parent-led intervention for anxiety for autistic children with ID and who speak for or no words. The intervention will combine evidence-based behavioural approaches for autistic children who speak few or no words with anxiety reduction strategies from the typically developing literature. Following development, the intervention will be conducted with families of autistic children who speak few or no words to provide proof of principle for reductions in anxiety related behaviors over 16 weeks. Intervention will be conducted in participants homes. Each family will be staggered using a multiple baseline design to ensure that it is the intervention that is leading to a reduction of anxiety, rather than other factors.

Who can participate?
Children with autism and anxiety, and their parents or carers.

What does the study involve?
Before proceeding to the intervention, participants (parents/carers) will be asked to complete a baseline assessment to rate anxiety related behaviours in their child daily. Parents/carers will also complete a selection of informant-report measures and a direct autism assessment will also

be completed with the child.
Once eligibility is confirmed and baseline assessments complete, parents/carers will take part in the 16-week intervention programme. The intervention will be delivered by a research assistant, under close supervision by a clinical psychologist and will be delivered in the participant's home or over video-conferencing software.
Parents will be asked to complete a range of outcome measures, including a daily diary of anxiety, during and after the intervention period. Direct observations of the child's anxiety will be conducted by the researcher. Teachers will also be invited to complete a daily diary of anxiety in school during the intervention period.

What are the possible benefits and risks of participating?
Benefits of participation; Each participant will receive an individualised feedback report summarising the results of the study. This study will help us to test a new parent-led intervention for anxiety for autistic children. If successful, this intervention could be made available to other parents/carers with autistic children displaying anxiety.
Risks/burdens of participation: For all families there is a time commitment required for the assessments and intervention which may impact on family life. Sessions will be scheduled to minimise disruption as much as possible.
As participants go through the intervention sessions, there is a chance that some of the strategies included in the intervention may result in temporary changes in their child's behaviour and/or anxiety. However, the researcher will work with families to ensure they are always working in their relative comfort zones, and that there are strategies in place to manage changes in behaviour.
Participation in this intervention will not impact rights to access services.

Where is the study run from?
Aston University (UK)

When is the study starting and how long is it expected to run for?
June 2018 to December 2022

Who is funding the study?
Autistica (UK)

Who is the main contact?
Dr Jane Waite, j.waite@aston.ac.uk

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Aston University #1597

Study information

Scientific Title
A parent-led intervention for anxiety in autistic children with severe to profound intellectual disability: A multiple baseline study of a novel intervention

Acronym
LADDERS

Study objectives
The aim of this study is to test whether a novel parent led intervention for anxiety in autistic children who use few or no words is associated with subsequent reductions in child anxiety symptomology and low mood and improved parental well-being.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2020, Research and Knowledge Exchange (Aston University, Aston Triangle, Birmingham, B4 7ET, UK; +44 (0)121 204 5069; m.richards3@aston.ac.uk), ref: #1597

Study design
Single-centre multiple baseline single case experimental study

Primary study design
Interventional

Secondary study design
Multiple baseline design

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Anxiety symptoms displayed by autistic children aged 4-15 with intellectual disability

Interventions
Current interventions as of 15/11/2021:
After screening and initial contact, eligibility will be assessed, and informed consent will be obtained. Eligible participants will enter the baseline phase of the trial where anxiety related behaviors will be monitored daily for either 6, 10 or 14 days (randomly assigned) via questions from validated measures of anxiety and behavior. Families where children showing stable or worsening anxiety throughout the baseline period will receive the intervention.
The intervention is a 16-week programme and will include existing strategies for anxiety management in typically developing children, and children with ASD and ID. Strategies will inform parents about escape maintained and anxious avoidance behaviors, supporting parental well-being, graded exposure techniques and strategies to overcome common barriers to exposure-based tasks. The intervention will be conducted individually with parents and a therapist trained in the intervention manual.
Pre-intervention measures will be completed in Week 1 of the intervention, post-intervention assessments will be completed in the final intervention session (Week 16) and again 8 weeks later (week 24).
Daily diaries of child anxiety will be collected every day during the intervention period, in addition to weekly measures of anxiety interference on functioning.
Observations of child anxiety will be conducted in Weeks 2, 9, 11, and 14 of the intervention period. A follow-up observation will be conducted in week 24.
Qualitative interviews regarding the acceptability and continued use of strategies learned from the intervention will be conducted in weeks 16 and week 24.

Previous interventions:
After screening and initial contact, eligibility will be assessed, and informed consent will be obtained. Eligible participants will enter the baseline phase of the trial where anxiety-related behaviors will be monitored daily for two weeks via questions from validated measures of anxiety and behavior. Families where children showing stable or worsening anxiety throughout the baseline period will receive the intervention.
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Daily diaries of child anxiety will be collected every day during the intervention period, in addition to weekly measures of anxiety interference on functioning.
Observations of child anxiety will be conducted in Weeks 2, 9, 11, and 14 of the intervention period.
Qualitative interviews regarding the acceptability and continued use of strategies learned from the intervention will be conducted in weeks 16 and week 24.

Intervention Type
Behavioural

Primary outcome measure
Parent report of daily child anxiety completed daily via an anxiety daily diary

Secondary outcome measures
Current secondary outcome measures as of 04/05/2022:
1. Researcher observed child anxiety observed at Weeks 2, 9,14 and 24
2. Parent-reported child mental health symptomology measured using the Mood Interest and Pleasure Questionnaire, the Anxiety Depression and Mood Scale and the Clinical Anxiety Screen for Intellectual Disability measured at Weeks 1, 16, and 24
3. Parent-reported Child sensory processing measured by the Sensory Experience Questionnaire at Weeks 1, 16, and 24
4. Parent-reported child repetitive behavior measured by the Repetitive behavior Questionnaire at Weeks 1, 16, and 24
5. Parent report of child behaviors that challenge measured by the Challenging Behavior Questionnaire at Weeks 1, 16, and 24
6. Parent report of their own well-being measured by the Hospital Anxiety and Depression Scale at Weeks 1, 16, and 24
7. Parent report of their ability to manage anxiety measures by the Controllability Beliefs Scale at Weeks 1, 16, and 24
8. Parent-reported impact of anxiety on family functioning measured by the Child Anxiety Life Interference Scale completed weekly during intervention at Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16
9. Teacher report daily child anxiety completed daily via an anxiety daily diary to provide convergent validity of parent report data
10. Parent-reported acceptability and continued use of learnt strategies measured by qualitative interviews at Weeks 16 and 24

11. Parent report of child sleep behaviours measured by the Children's Sleep Habits Questionnaire (CSHQ) at Weeks 1, 16, and 24

Previous secondary outcome measures:
1. Researcher observed child anxiety observed at Weeks 2, 9, 11 and 14 (updated 15/11/2021: observed at Weeks 2, 9, 11, 14 and 24)
2. Parent-reported child mental health symptomology measured using the Mood Interest and Pleasure Questionnaire, the Anxiety Depression and Mood Scale and the Clinical Anxiety Screen for Intellectual Disability measured at Week 1, Week 16 and Week 24
3. Parent-reported Child sensory processing measured by the Sensory Experience Questionnaire at Week 1, Week 16 and Week 24
4. Parent-reported child repetitive behavior measured by the Repetitive behavior Questionnaire at Week 1, Week 16 and Week 24
5. Parent report of child behaviors that challenge measured by the Challenging Behavior Questionnaire at Week 1, Week 16 and Week 24
6. Parent report of their own well-being measured by the Hospital Anxiety and Depression Scale at Week 1, Week 16 and Week 24
7. Parent report of their ability to manage anxiety measures by the Controllability Beliefs Scale at Week 1, Week 16 and Week 24.
8. Parent-reported impact of anxiety on family functioning measured by the Child Anxiety Life Interference Scale completed weekly during intervention at Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16
9. Teacher report daily child anxiety completed daily via an anxiety daily diary (added 20/07 /2021: to provide convergent validity of parent report data)
10. Parent-reported acceptability and continued use of learnt strategies measured by qualitative interviews at week 16 and week 24

Overall study start date
01/06/2018

Completion date
20/12/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/11/2021:
1. Parent/carers of children 4 -15 years with a clinical diagnosis of autism or meeting cut-off for autism on the Social Communication Questionnaire
2. Parent/carers of children who speak few words or odd words only on the Wessex Questionnaire (added 20/07/2021: this is for initial screening purposes. The presence of intellectual disability will be assessed during the baseline assessment stage of the intervention)
3. Parent report that child experiences anxiety on 'more days than not' or reports that anxiety significantly impacts their quality of life on a weekly basis
4. Parents report that their child engages in avoidance or escape behaviour in response to situations that appear to be related to the child's anxiety. A consensus decision on the functionality of behaviours will be made by the PI (Dr Jane Waite; Clinical Psychologist) and Dr Joanne Tarver.
5. Parent agrees to child's GP and psychology/behavioural/psychiatry team (if applicable) being advised of involvement in the study.
6. Child currently living with consenting parent/carer full-time

Previous inclusion criteria:
1. Parent/carers of children 4 -12 years with a clinical diagnosis of autism or meeting cut-off for autism on the Social Communication Questionnaire
2. Parent/carers of children who speak few words or odd words only on the Wessex Questionnaire (added 20/07/2021: this is for initial screening purposes. The presence of intellectual disability will be assessed during the baseline assessment stage of the intervention)
3. Living within 2 hours of Aston University (for pragmatic reasons it will not be feasible for the research team to travel further than this on a weekly basis)
4. Parent report that child experiences anxiety on 'more days than not' or reports that anxiety significantly impacts their quality of life on a weekly basis
5. Parents report that their child engages in avoidance or escape behaviour in response to situations that appear to be related to the child's anxiety. A consensus decision on the functionality of behaviours will be made by the PI (Dr Jane Waite; Clinical Psychologist) and Dr Joanne Tarver.
6. Parent agrees to child's GP and psychology/behavioural/psychiatry team (if applicable) being advised of involvement in the study.
7. Child currently living with consenting parent/carer full-time

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
20

Key exclusion criteria
Current exclusion criteria as of 15/11/2021:
1. Child has started any medication within 6 weeks of baseline measurement for any psychiatric diagnosis or for behavioural management reasons or there are planned medication changes for the duration of the intervention period
2. Child is in receipt of current focused regular input (fortnightly or more) from a clinical psychologist or related team specifically for anxiety, or that such input is planned to start during the time that the child is enrolled in the intervention
3. Current social services involvement with family for the purposes of child protection (active safeguarding concerns)
4. Parent/carers who do not have sufficient literacy to understand study questionnaires or engage in research related activities
5. Improvements in anxiety during baseline period (i.e., a negative trend during the baseline period)

Previous exclusion criteria:
1. Child has started any medication within 6 weeks of baseline measurement for any psychiatric diagnosis or for behavioural management reasons or there are planned medication changes for the duration of the intervention period
2. Child is in receipt of current focused regular input (fortnightly or more) from a clinical psychologist or related team specifically for anxiety, or that such input is planned to start during

the time that the child is enrolled in the intervention
3. Current social services involvement with family for the purposes of child protection (active safeguarding concerns)
4. Parent/carers who do not have sufficient literacy to understand study questionnaires or engage in research related activities
5. Improvements in anxiety during baseline period (i.e., a negative score is calculated when subtracting median week 3 anxiety from median week 2 and the participant has shown a 6-point reduction on subscales of the ADAMS)

Date of first enrolment
01/10/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aston University
School of Psychology
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Sponsor information

Organisation
Aston University

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Sponsor type
University/education

ROR
https://ror.org/05j0ve876

Funder(s)

Funder type
Charity

Funder Name
Autistica

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
The findings for the multiple baseline study will be published in high impact peer-reviewed journal. Other publications will be planned at a later date.

Added 20/07/2021: Protocol publication statement: The intervention protocol will be published shortly.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The current data-sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date