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SupporTing pARents and their autistic Children through Anxiety Treatment (STAR-CAT)

Submission date
10/01/2025

Recruitment status
Recruiting

Registration date
20/01/2025

Overall study status
Ongoing

Last Edited
16/09/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
An online, parent-led, therapist-support intervention called OSI (Online Support and Intervention for child anxiety) was previously co-designed. Previous research has found OSI to be clinically effective, cost-effective and acceptable to clinicians and families. OSI has now been adapted to meet the needs of autistic children with anxiety problems and their families. This adapted version of OSI is called OSI-A. The STAR-CAT study will test whether OSI-A can make treatment for anxiety problems among autistic children more accessible without compromising children's outcomes.

Who can participate?
Children aged 5-12 years old, with either diagnosed autism or suspected autism, about to receive treatment for anxiety problems

What does the study involve?
The study involves being randomly allocated to either OSI-A or Treatment as Usual (TAU) after completing questionnaires at the time of enrollment. These questionnaires will be repeated at 24 weeks and 48 weeks post-randomisation. Please note that if the child does not have an autism diagnosis, they will need to complete 'consent to screen' and a questionnaire before enrolment to check eligibility for the STAR-CAT study.

What are the possible benefits and risks of participating?
Benefit:
Children taking part in this study will all receive treatment. Those in the OSI-A arm will receive treatment from therapists who will have received training from experts in child anxiety treatments (via an e-learning platform) and will have access to a novel, online intervention that may bring efficiencies for families.

Time burden: Participants will be required to complete more measures than they would in usual clinical practice. Families will receive £10 for each completed follow-up questionnaire to compensate for the extra time spent on research-related questionnaires within this trial.

Novel treatment delivery: Families in the OSI-A arm of the trial will receive an adapted version of an established online treatment but the online version has not yet been systematically evaluated. As such we cannot be sure what the outcome will be.

Audio recordings: Audio recordings will be made during qualitative interviews and some participants may feel cautious about this.

Where is the study run from?
University of Oxford, UK

When is the study starting and how long is it expected to run for?
April 2024 - March 2028

Who is funding the study?
National Institute for Health and Social Care Research (NIHR)

Who is the main contact?
Trial Manager, starcat@psy.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
343622

Central Portfolio Management System (CPMS)
65706

National Institute for Health and Care Research (NIHR)
157696

Protocol serial number
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Code:

Study information

Scientific Title
Clinical and cost-effectiveness of adapted online parent-led treatment compared to treatment as usual for autistic children with anxiety problems in clinical services: A randomised controlled trial.

Acronym
STAR-CAT

Study objectives
To evaluate the parent-reported clinical effectiveness of a brief parent-led cognitive behavioural treatment (CBT) delivered by the OSI-A platform with therapist support (OSI-A + therapist support) for the treatment of anxiety in autistic children compared to 'treatment as usual' (TAU) in child mental health services.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/01/2025, London - Central Research Ethics Committee (3rd Floor, 3 Piccadilly Place, London Road, Manchester, M1 3BN, United Kingdom; +44(0)207 104 8282; Londoncentral.rec@hra.nhs.uk), ref: 24/LO/0875

Primary study design
Interventional

Study design
Two-arm multi-site randomized controlled non-inferiority trial with a nested pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety problems in autistic children aged 5-12

Interventions
This is a two-arm, multi-site, randomised controlled non-inferiority trial, with a nested pilot trial, to evaluate the clinical and cost-effectiveness of a brief parent-led cognitive behavioural treatment (CBT) delivered by the Online Support and Intervention for autistic children (OSI-A) with therapist support compared to treatment as usual in child mental health services and to explore parent, child, and therapists' experiences. Randomisation will be performed using a fully validated randomisation system Sortition® with a non-deterministic minimisation algorithm to ensure child age (<=8; >8), gender, service type (school-based, specialist neurodevelopment service, or other), baseline anxiety-associated interference (measured by CAIS-P <=25; >25), and the status of autism (likely to be autistic; confirmed autistic) is balanced across the two groups. Participating families will be randomised to either OSI-A with therapist support or to usual

treatment within child mental health services to establish whether OSI-A plus therapist support can reduce therapist time without compromising outcomes for autistic children with anxiety problems. Participating clinics offering child mental health services will receive training on trial procedures, including identifying eligible participants. They will also be given training on how to use the OSI-A platform.

Participating families will be identified by their clinical teams. If the child has not yet received an autism diagnosis, clinicians need to ensure that the possibility of autism has been discussed with families before this study is introduced to the family. Clinical teams will follow their usual procedures to identify the child's primary presenting problem. Where the clinical teams identify the child has an autism diagnosis, or is considered to be likely to meet criteria for an autism diagnosis, and has a primary anxiety problem, they will be considered to be potentially eligible for the trial. Potentially eligible families will be provided information about the study by their clinician and, if interested, will provide verbal consent for the clinician to confirm that the study inclusion criteria are met (and exclusion criteria are not) and to send the family a link to the Patient Information Sheet and Informed Consent Form. If the child does not have an autism diagnosis, then the family will be required to complete the SCQ online to confirm eligibility. The clinician will provide parents/caregivers with an information pack (via online link or paper) containing information sheets about the study for the parent/caregiver and the child (age-appropriate and in various formats, e.g., video). The information sheets will provide further information about the study and what would be expected of the participants alongside contact details for the study team (email and phone number) so that they can be contacted to answer any questions.

The family will have the opportunity to complete online consent to the main study (if the child has a confirmed autism diagnosis) or consent to screen (if SCQ is required to confirm eligibility). Once the SCQ is complete, and the score confirms eligibility, the family will be able to consent to the main study. If the SCQ indicates that they are ineligible, the family will be informed, and the treating clinician will be asked to provide alternative treatment. The research team will be informed of the results, using the family's unique trial ID number, which they will use to follow up with the therapist to ensure alternative treatment has been arranged. The screening data (including SCQ score) will be retained to monitor recruitment and reasons for ineligibility to ensure parity in access. The parents/caregivers who consent to the main study will then be asked to complete online self-report baseline assessments (all questionnaires). At the end of the questionnaires, the parent/caregiver can indicate whether the child would like to provide (optional) assent to take part and complete the child self-report questionnaires. Participants will be randomised within 1 month of expression of interest and allocated to the intervention arm or treatment as usual (TAU). Families allocated to the intervention arm will be delivered OSI-A + therapist support by a member of the clinical team. OSI-A incorporates routine outcome measures for clinical purposes, but these measures are also available to the research team through the OSI (pseudo-anonymised) researcher portal. Families allocated to TAU will receive the treatment their clinical team would usually offer, and information will be gathered on the nature of this treatment through therapist logs.

Participating parents will be sent a link to complete post-treatment and follow-up assessments (questionnaires) online 24 and 48 weeks after randomisation. Once parents have completed their questionnaires, children who have assented will have the opportunity to complete their self-report questionnaires.

Qualitative interviews will be conducted with a subgroup of parents, children, and clinicians from both arms (n= 45-60), purposively sampled based on demographics and treatment outcomes, to explore clinicians', parents', and children's experiences of treating child anxiety. Clinicians will be

provided with an information sheet for this part of the study, and those who participate in these interviews will provide consent at the beginning of the interview. Additionally, multimodal data will be collected from up to 50 children invited from the wider trial population. Children will be able to choose from a creative 'menu' of participation modes, co-designed with children, parents, and clinicians, building on established methods. This menu will offer a range of modalities (e.g., a digital pinboard for images and memes) for children to share their experiences of anxiety. Children will be invited to contribute at two timepoints: pre-intervention and post-intervention. Parents will have the opportunity to provide optional consent for their child to take part in this activity when they sign the main consent form.

Intervention Type
Behavioural

Primary outcome(s)
Clinical effectiveness is measured using the Child Anxiety Impact Scale- Parent Report (CAIS-P) at 48 weeks post-randomisation

Key secondary outcome(s)
1. Clinical effectiveness is measured using the following child-reported tools at 24 weeks post-randomisation:
1.1. Child Anxiety Impact Scale (CAIS-C)
1.2. Anxiety Scale for Children with Autism Spectrum Disorder (ASC-ASD)
2. Clinical effectiveness is measured using the following tools at 48 weeks post-randomisation:
2.1. Parent-reported Child Anxiety Impact Scale (CAIS-P)
2.2. Parent-reported Anxiety Scale for Children with Autism Spectrum Disorder (ASC-ASD -P)
2.3. Parent-reported Outcome Rating Scale (ORS)
2.4. Common comorbid emotional and behavioural problems Strengths and Difficulties Questionnaire (SDQ)
2.5. Child- and parent-reported progress against valued outcomes using bespoke Likert scales
2.6. Parent confidence and skills to apply treatment strategies using bespoke Likert scales
3. Cost-effectiveness is measured using the Child Quality Adjusted Life Years (QALYs) derived from the CHU-9D proxy version, i.e. parent -report on child, at baseline, 24 weeks post-randomisation and 48 weeks post-randomisation

Completion date
31/03/2028

Eligibility

Key inclusion criteria
Child
1. Is aged 5-12 years at the time of parental consent
2. Autism diagnosis or positive screen on autism questionnaire (SCQ)
3. The primary problem is anxiety

Parent/Carer:
1. Is the parent/carer of a child who meets the study inclusion criteria
2. Has sufficient English language, or available assistance, to complete measures/ access interventions

3. Has access to the internet (NB. Devices and financial support for data access can be made available).
4. Is willing and able to provide consent.

Therapists (for qualitative interviews only)
1. Provides psychological treatment to children in participating services
2. Willing and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Child
1. Has co-morbid conditions that mean therapeutic strategies are clinically inappropriate (diagnosed profound or severe intellectual disability, suicidal intent/ recurrent or potentially life-limiting self-harm),
2. Is identified by social services due to child protection concerns.

Parent/carer
1. Has been diagnosed with a profound or severe intellectual disability or severe mental health problem that is likely to interfere with treatment delivery.

Therapist
There are no exclusion criteria for Therapists.

Date of first enrolment
06/01/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Barnardos North Cumbria MHST
North Cumbria Mental Health Support Team
Suite 2, Riverside House, Warwick Road
Carlisle
England
CA1 2BS

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
Bridge Park Plaza
Bridge Park Road
Leicester
England
LE4 8PQ

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way

Darlington
England
DL2 2TS

Study participating centre
West London NHS Trust
1 Armstrong Way
Southall
England
UB2 4SD

Study participating centre
Derriford Hospital
University Hospitals Plymouth Nhs Trust
Derriford Road, Derriford
Plymouth
England
PL6 8DH

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Trust Headquarters, Redesmere
the Countess of Chester Health Park
Liverpool Road
Chester
England
CH2 1BQ

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
England
SO19 8BR

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Block A, Willerby Hill
Beverley Road

Willerby
Hull
England
HU10 6FE

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Kings Drive
Prescot
England
L34 1PJ

Study participating centre
NHS Hampshire and Isle of Wight Integrated Care Board
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes