

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

Submission date 10/01/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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?

Kelsey Armitage (Trial Manager), starcats@psy.ox.ac.uk

Study website

<https://osiresearch.org.uk/star-cat/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

343622

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 65706, NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Code: NIHR157696

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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community, Home, Hospital, Internet/virtual, School

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2024

Completion date

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

Age group

Child

Lower age limit

5 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

Planned Sample Size: 650; UK Sample Size: 650

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

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

Hellesdon Hospital

Drayton High Road

Norwich

United Kingdom

NR6 5BE

Study participating centre

Belfast City Hospital

51 Lisburn Rd

Belfast

United Kingdom

BT9 7AB

Study participating centre

Barnardos North Cumbria MHST

North Cumbria Mental Health Support Team

Suite 2, Riverside House, Warwick Road

Carlisle

United Kingdom

CA1 2BS

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

Study participating centre
West Berkshire Council
Council Offices
Market Street
Newbury
United Kingdom
RG14 5LD

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
United Kingdom
GL3 4AW

Study participating centre
The Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF

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

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

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

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

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

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

Study participating centre

Solent NHS Trust

Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre**Tonna Hospital**

Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

Study participating centre**Sunderland Royal Hospital**

Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre**Humber Teaching NHS Foundation Trust**

Trust Hq, Block A, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6FE

Study participating centre**Mersey Care NHS Foundation Trust**

V7 Building
Kings Business Park
Kings Drive
Prescot
United Kingdom
L34 1PJ

Study participating centre**Alder Hey Hospital**

Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre**NHS Hampshire and Isle of Wight Integrated Care Board**

Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

University of Oxford

Sponsor details

Research Governance, Ethics and Assurance
Joint Research Office, Boundary Brook House, Churchill Drive, Headington
Oxford
England
United Kingdom
OX3 7GB
-
RGEA.Sponsor@admin.ox.ac.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.ox.ac.uk>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/03/2029

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date