Professor Cathy Creswell
TOPIC Research Group
Departments of Experimental
Psychology and Psychiatry
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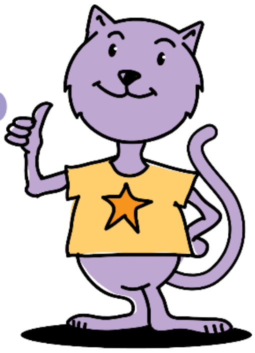
STAR-CAT

SupporTing pARents and their autistic Children through Anxiety Treatment



Chief Investigator: Professor Cathy Creswell

PARENT INFORMATION SHEET

Version 3.0 04 Dec 2025, IRAS ID: 343622, REC: 24/LO/0875

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you and your family. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Important note!

Throughout this information sheet we refer to 'autistic children'. Children who have an autism diagnosis are eligible to take part however children **do not** need to have had an autism diagnosis to take part.

Children can take part if you, their parent/carer, and the therapist you are working with consider that it *might* be possible that your child would get an autism diagnosis if they were assessed. This does not mean that they are autistic; it is just possible that they might be.

In the document below we refer to 'autistic children' as a shorthand for **autistic children and children who might be autistic.**

What is this all about?

We are carrying out a study to assess a new **treatment** for anxiety problems in autistic children**. This treatment** involves parents/carers working through content on a website with therapist support (over the phone or on a video call) throughout. We are comparing this treatment to the **usual treatment** that is currently being offered to treat anxiety problems in autistic children. The study is taking place across the UK, including in the clinical service that will be delivering your child's treatment.

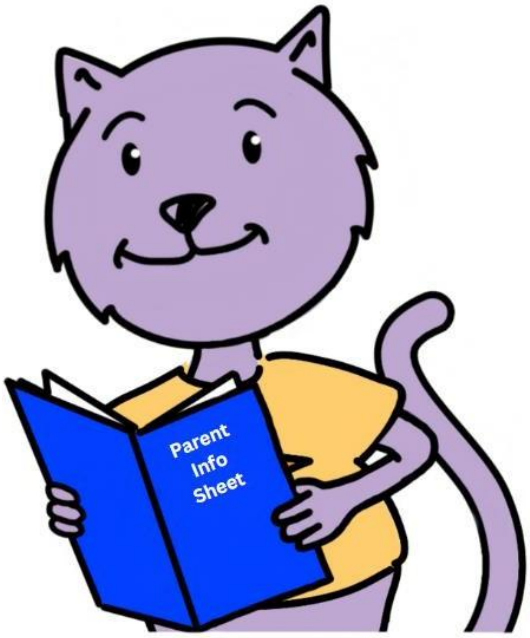
During the first 8-months of the study we will confirm whether we are able to recruit participants to take part in STAR-CAT as expected, that we have enough participants completing all of the follow up questionnaires, and that there are no problems with the new treatment or the study procedures before moving on to complete the study.

We would like to invite you to take part.

In this leaflet, there is some information that we hope will help you to decide whether you would like to take part.

We will also provide some information for your child.

What can you find in this leaflet?



A BRIEF OVERVIEW

You have been given this leaflet because your child:

- Has had a diagnosis of autism OR you and the clinical service that you are working with consider that it is possible that your child would get an autism diagnosis if they were assessed.
- Is between **5 and 12** years old.
- Is about to start treatment for problems with **anxiety**.

You will be offered one of two **treatment options** as part of this research.

Your family will be **randomly allocated** to one of these options (i.e. a computer will determine which group you will be in).

We are planning to recruit 650 children (and parent/carers) to participate in the STAR-CAT study and 10-15 therapists to take part in an interview.

What are the treatment options?

The first treatment option involves working through an online platform with therapist support:

- You will be given access to a website that will help you to help your child overcome problems with anxiety. The website content is based on an effective treatment for child anxiety problems that has been adapted to meet the needs of autistic children and their families by working closely with families, clinicians, and other autism experts. You will be able to access this website by using a computer, laptop, tablet, or smartphone.
- You will get weekly support from a therapist (on the telephone or video call).

The second treatment option is treatment as usual:

- This will be whatever treatment your child's therapist would usually offer.
- Your therapist will be able to tell you what it will involve.

What else will I be asked to do?

- If your child has not been diagnosed as autistic by a medical professional, then you will be sent a link via email to answer an online questionnaire which focuses on child's developmental history at the beginning to ensure your child is eligible for this study.
- Once eligibility has been confirmed, and you complete the consent form for the main study, you will then be emailed another link (within 3 working days) to fill in some online **questionnaires**. The questionnaires include questions about you, your family, your occupation and earnings. These are followed by some questions about your child and how they have been feeling, including questions about their anxiety and how much their worries cause problems for you and them. There are also some questions about your health and your child's education over the last three months. The questionnaire ends asking you about any contact you have had with other services. We will contact you via email, text, or phone call for to remind you to complete the questionnaires if required.
- After completing these questionnaires, the last question will ask whether your child would like to complete some questionnaires relating to how they have been feeling and how anxiety has been affecting their lives. These are completely optional, but if your child would like to complete these, your child will need to complete an assent form to confirm they are happy to do so. The questionnaires will be available to complete once assent has been confirmed. Your child will have one week to complete the questionnaires before being randomly allocated a treatment to not delay the start of treatment.
- You will then be randomly allocated to either the online platform with therapist support or treatment as usual. This will happen within 3 working days, once all of the questionnaires have been completed, i.e., your questionnaires and your child's questionnaires (if applicable).
- We will invite you and your child (if applicable) to complete some more questionnaires **24 and 48 weeks** from now so we can see how things are going. We may send you reminders to complete these questionnaires via email, text, or phone call.

- We will also ask some parents and children, and also some of the therapists who have led the online therapy, to take part in an optional **interview** to tell us a bit more about how they found taking part.

SOME IMPORTANT POINTS

You and your child do not have to take part and deciding not to take part will not affect your child’s future treatment.

- Families who do not take part will be offered **treatment as usual**.
- You and your child have the **right to withdraw** from the treatment, assessments or interviews at any time, even during the sessions. No further data will be collected but any data that has already been collected will be used in the analysis.
- The research team may contact you to remind you to complete study activities (e.g., questionnaires), in order to prevent delays to treatment.

You won’t be able to choose which treatment your child will receive in the study.

- During the study, your child will only receive the treatment that they have been allocated.
- At the end of the study, your child’s therapist will review your child’s progress and discuss any next steps with you.

All information and research data will be kept secure and in confidence.

- Please see page 14 for more details about how we **use your information** and **keep it safe**.

A CLOSER LOOK AT THE STUDY

Autistic children have a higher rate of mental health problems than their peers, in particular anxiety.

- We have treatments that work well for child anxiety problems in non-autistic children, including an online treatment with therapist support.
- This treatment has not been delivered to autistic children until now as anxiety in autism often presents differently.
- We have worked closely with families, clinicians and other autism experts to adapt these treatments for autistic children.
- To find out if this new treatment also helps treat anxiety problems, we are comparing the new online treatment to the approach that your clinic is currently taking.

The aim of this study is to compare a new online program to help parents to help their children (with therapist support), to treatment as usual:

- The new online platform involves 9 online modules which are accompanied by weekly calls for the parent/carer with a clinician and then a final phone/video call 4 weeks after the final treatment session.
- Treatment as usual will be whatever your clinic currently offers to help autistic children with anxiety problems.
- The treatment that families get is decided at random, using a computer programme.

This research will help us to make future treatments as effective, accessible, and efficient as possible. We hope this will help give as many children as possible the best chance of support and recovery.

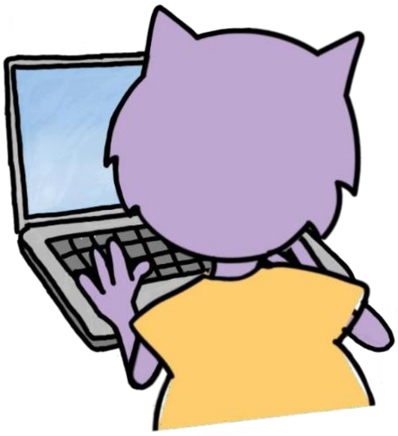
More about the online treatment

The online treatment being adapted for this study is called **OSI** (Online Support and Intervention for child anxiety). OSI has already been evaluated in a number of research studies, and has been found to be effective for treating child anxiety problems and also acceptable to children and families. You can read more about previous OSI research here.

Parents/carers have previously told us…

- “OSI is exactly what we needed. We love the flexibility of it”
- “The course supported and empowered me”
- “OSI is giving me confidence as a parent”

The new version of OSI that is being tested in the STAR-CAT study will retain all the features of the original OSI treatment, but has been adapted for use with autistic children and their families. We worked closely with families with lived experience to ensure that the new OSI is acceptable.



What we will ask you and your child to do:

You are invited to take part in the study.

You will be asked to complete an online consent form for the main study for you and your child or consent to screen if your child does not have a confirmed autism diagnosis

If your child does not have a confirmed autism diagnosis, you are required to complete an online questionnaire to check your child is eligible to take part.

You would then proceed to complete the online main consent form if your child is eligible. If your child is not eligible, you and your clinician will be informed in order to arrange suitable treatment.

You (and your child if they are happy to) will be asked to fill in some online questionnaires. Your child will be asked whether they would like to provide (optional) assent to complete some online questionnaires at this point.

Your family will be randomly assigned to one of the two treatments and you will be emailed with the result.

Using images and memes, we may invite your child to tell us about their experiences with anxiety (on a digital pinboard) before and after they complete their treatment (optional)

Your family will receive the treatment (see Treatment A & B on next page).

You (and your child if they are happy to) will be asked to fill in some online questionnaires again 24 and 48 weeks after you agree to take part.

You and your child may also be invited to be interviewed about your experience of the study (optional).

After the final session, your child's therapist will talk to you about what happens next.

What happens in Treatment A and B?

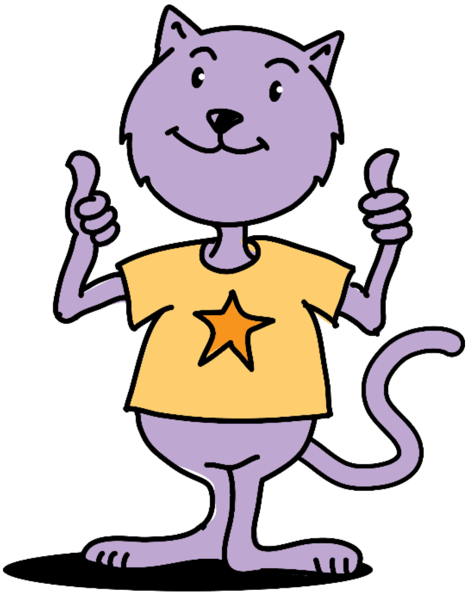
Treatment A

- Parent has access to a website with information and activities to work through.
- Parent has 10 telephone/video call sessions with a therapist over approximately 13 weeks (approximately 30 minutes each).
- Questionnaires to complete on the website to track your child's progress through treatment.

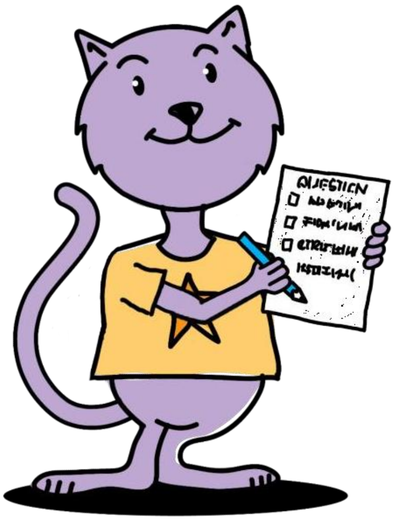
Treatment B

(treatment as usual)

- The usual treatment currently being offered for child anxiety.
- Your child's clinician will be able to give you more information on what this would look like.



What will happen during the study?



- We will ask you and your child to fill out some **online questionnaires** about your child's anxiety and the impacts this has. Additionally there will be some questionnaires related to your child's autistic traits and behaviours. You will also be asked some questions about your general lifestyle. Reminders will be sent via email and/or text to compete these questionnaires.
- You can still take part in the study if your child does not want to complete the questionnaires.
- You will need to keep a log of all health-related appointments that you and your child attend and any costs occurred, as you will be asked for this information at the 24 and 48 week follow up.
- You and your child's participation in the study is likely to last approximately **12 months** in total.
- We may ask you and your child to take part in an **optional interview (via telephone or video call)** after the treatment.

The optional interview will involve you talking with a researcher about **how you and your child found the treatment** and what you think about the work we are doing. When we write up our research, we will include some **quotes** from the interviews so that people know the important things that were said. We **won't use any real names**, so people won't be able to identify who said what. (The interviews will be audio recorded, and transferred within 24 hours to our secure system as detailed on page 12. These recordings will be deleted when they have been transcribed and checked.)

What are the advantages of taking part?

- By taking part, you and your child will be helping us to try to find the best way to **treat anxiety problems** in autistic children and we will learn a lot from this for the future.

Will my General Practitioner (GP) be informed of my participation?

- Your child’s GP will be notified of study participation and will be provided with the Participant Information Sheet.

Will my taking part in the study be kept confidential?

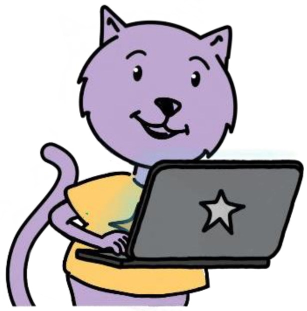
- Yes, each participant in the study is given a **participant number**. We will use this participant number to label all information we collect about you and your family. Therefore, all information is pseudonymised.
- All the study data is owned by the University of Oxford. It will be kept locked away or on secure computer servers in locked rooms with restricted access. Responsible members of the University of Oxford, regulatory bodies, and from the NHS Trust(s), where it is relevant to me and my child taking part in this research, may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.
- Only your clinical team and members of the research team will have access to personal information you give us for the purposes of the study.

- Both the files and the drive on which we store research files have restricted access. Only members of the research team have access.
- The data collected about you will be preserved and made available in a form in which you cannot be identified, so that it can be consulted and re-used by researchers and collaborators.

- Your email addressed will be stored on the research database in order to send you the questionnaires for completion.

Will I be reimbursed for taking part?

- **Each family will get a £10 voucher when they complete the questionnaires at each follow up visit** as a thank you for giving up their time to complete the questionnaires.
- Parents who take part in the interview will get a **further £20 voucher** as a thank you for their time.
- Children who take part in the interview will get a **further £20 voucher** as a thank you for their time.
- Children who participate in the 'digital pinboard' will get a **further £10 voucher** as a thank you for their time.
- If helpful, families can be **reimbursed for the cost of the data** that was used when they took part in the online support.



- An additional £10 voucher that could be used to **help with childcare costs** to enable parents to complete the measures can be provided if helpful. This can be discussed with the research team when joining the study.
- If you do not have a device available for accessing the internet, devices can be loaned for the duration of the study so that you can complete online measures and access the new treatment (if applicable). The devices will need to be returned after you complete the final questionnaires 48-weeks after you agree to take part. We will contact you to arrange a convenient time for a courier to collect the device from you.

What are the disadvantages of taking part?

- You and your child will have to complete more questionnaires than you would normally do as part of your usual care.
- Some of the questions will involve discussing thoughts and feelings that may be upsetting, however, the questions are similar to the ones that are used in clinical care. If you have any concerns, please contact your clinician or the research team. If you no longer want to

participate, you and your child can withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights or medical care, and with no obligation to give the reason for withdrawal.

Other assurances:

- We don't foresee any harm coming to you or your child as a result of taking part in this study. All of the researchers at the University of Oxford have had criminal record checks and have been approved by the University of Oxford to work with children.

If you have any concerns about any part of the study, you should ask to speak to Professor Cathy Creswell, the chief investigator (contact details on the last page of this information sheet).

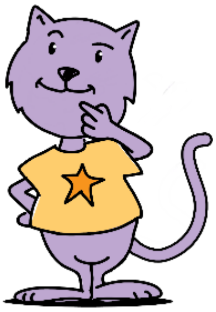
What will happen to my data?

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is a task that we perform in the public interest. The University of Oxford, as the sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly.
- We will be using information that you have given us and from your child's clinician and medical records in order to undertake this study and will use the minimum personally identifiable information possible.
- We at the University of Oxford will keep contact information about you until the end of the study unless you consent to be contacted for future research. In this case, we at the University of Oxford will keep your contact details for three years after youngest participant reaches 18 years old and then securely destroyed. The contact details will be stored separately from the study data on a secure university system.

- You or your child do not have to take part in any of the future research projects, you are free to choose what projects to take part in. You can also request that these details are deleted at any time by contacting the study team.
- If you agree to your details being held to be contacted regarding future research, we will keep a copy of your consent forms, these will be held securely at the University of Oxford, separately from the main study database.
- We will store the pseudonymised research data and research documents with personal information, such as consent forms, securely at the University of Oxford for three years after youngest participant reaches 18 years old and then securely destroyed.
- The local NHS Trust may use your name or your child's name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study. A copy of the consent form from this study will be kept in your child's medical records for as long as those records are retained. They will keep any other identifiable information about you and your child (consent forms) from this study for 3 years after youngest participant reaches 18 years old and then securely destroyed.
- Data collected about you and your child in this study will be preserved and may be made available to researchers outside the University in a form that does not identify your child or your family.
- Your GP practice will be informed that you and your child are taking part in this study by post or email.
- Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights.
- You can find out more about how we use your information by contacting Chief Investigator Prof Cathy Creswell (cathy.creswell@psych.ox.ac.uk) or the research team (starcat@psy.ox.ac.uk).

ADDITIONAL IMPORTANT DETAILS

What will happen if I don't want to carry on with the study?



- Participation in this study is voluntary. It is okay if you, or your child, changes your mind at a later stage.
- Not taking part will not affect your legal rights or the medical care you and your child receive from the NHS.
- If you do withdraw, no further data will be collected but any data that has already been collected will be used in the study analysis.

What will happen to the results of this study?

The results of this study will be published in academic journals, on the university website and in an open science archive, and the findings will be presented at conferences. We may also publish summaries of key findings for the wider public and to people taking part in the study. You and your child would not be identified from any report or publication placed in the public domain.

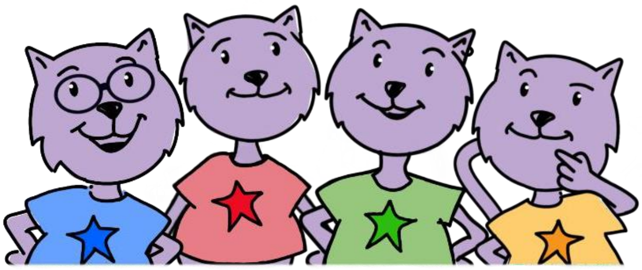
Who is organising and funding the study?

This study is sponsored by the University of Oxford. It is funded by the National Institute for Health and Care Research (NIHR). The research staff are from the University of Oxford and the Chief Investigator is Prof Cathy Creswell, Professor of Developmental Clinical Psychology at The Oxford Psychological Interventions for Children and adolescents (TOPIC) research group, based in Experimental Psychology.

Please note that the University of Oxford may receive royalties or consultancy fees associated with the distribution of OSI-A outside of research trials; however, no members of the research team receive any personal financial reward for the use of OSI. Participants will not share in any profits the University of Oxford may receive.

How have patients and the public been involved in this study?

The online platform, which delivers the new treatment, was developed in collaboration with autistic children and their parents/carers, NHS clinicians, and other autism and anxiety experts. We have worked with children and parents to make sure the study procedures are acceptable to families.



Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by London - Central Research Ethics Committee.

What if there is a problem...?

We don't expect anything bad to happen to you/your child as a result of taking part in this study, but in the unlikely event it does:

- Please speak with the research team on starcat@psy.ox.ac.uk. They will do their best to answer your questions.
- The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate no-fault insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to

someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

- NHS indemnity also operates in respect of the clinical treatment which is provided.

… and what can I do about it?

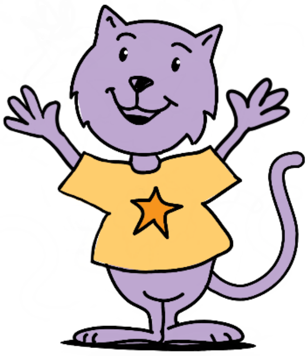
If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact:

- **Professor Cathy Creswell** (see details at the end of this information sheet), or
- You may contact the **University of Oxford Research Governance, Ethics and Assurance Team** office, email: RGEA.Sponsor@admin.ox.ac.uk on 01865 616 480.
- The **Patient and Client Council (PCC)** is a confidential service Independently representing the interests of the Public in Health and Social Care. They can provide you with support for any complaints or queries you may have regarding the care you received. PCC is unable to provide information about this research study. Please contact the PCC team using following the link: https://pcc-ni.net/.

WHAT HAPPENS NOW?

If you are happy to take part:

- Fill out online consent forms to show you are happy for **you and your child** to take part. You will be able to download a signed copy and this will also be sent to you via email.
- We will also ask **your child to agree to take part** and fill out an online form for themselves (optional).
- We will send a short letter to your child's GP letting them know that they are taking part.



If you <u>don’t</u> want to take part:

- You don’t have to do anything more and your child will get **treatment as usual**.

Participation in future research:

If you agree to us contacting you again in the future, your contact details will be held separately from this study data on a secure, restricted access University of Oxford drive. We will not pass your details on to others and any future contact will come from our research team in the first instance. Agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish.

What if I have questions?

If you have any questions or concerns about any aspect of the treatment or the research, please speak to a member of your clinic team or contact one of the research team:

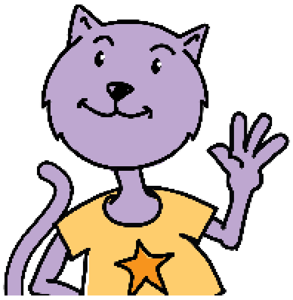
Trial Manager: Kelsey Armitage

Email: starcat@psy.ox.ac.uk

Phone: 01865 618175

Chief Investigator: Cathy Creswell

Email: cathy.creswell@psych.ox.ac.uk



THANK YOU!

For reading about our study

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