

FUNDED BY

NIHR | National Institute
for Health Research

NIHR | Oxford Biomedical
Research Centre

NIHR | Applied Research Collaboration
Oxford and Thames Valley

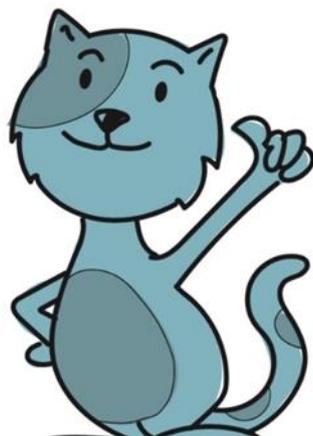
Co-CAT

Child Anxiety Treatment in the context of COVID-19

Chief Investigator: Professor Cathy Creswell

PARENT INFORMATION BOOKLET

Version 1.1 08.10.2020, IRAS 288074





What is this all about?

We are carrying out a study to compare a **parent-led treatment** which involves access to content on a website and with therapist support throughout for anxiety difficulties in children with the **usual treatment** that is currently being offered to treat child anxiety difficulties. The study is taking place across England, including in the clinical service that will be delivering your child's treatment.

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?

Page 3-4	A brief overview of the study.
Page 5	Some important points about what taking part will mean
Page 6	A closer look at the study
Page 7-9	What we will be asking you and your child to do
Page 10-11	The advantages and disadvantages of taking part
Page 12	Details about how we keep your information safe
Page 13-14	What if there is a problem and what can I do about it
Page 15	What next?



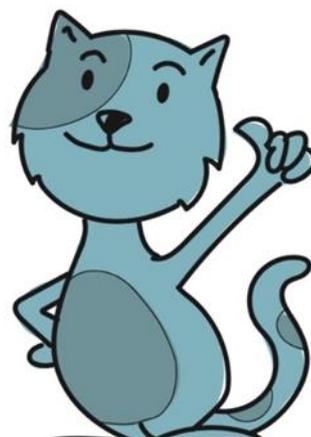
A BRIEF OVERVIEW

You have been given this leaflet because your child:

- Is aged **5 - 12** years old.
- Has come to the clinic because of problems with **anxiety**.

You will be offered one of two **treatment delivery 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).





What are the treatment options?

The first treatment option is access to an online platform and therapist support:

- you will be given access to a website that will help you to help your child overcome problems with anxiety
- you will get weekly support from a therapist (on the telephone)

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?

- We will ask **you and your child** to fill in some online **questionnaires** at the beginning of the study. We will invite you to complete some more questionnaires **14 and 26 weeks** from now so we can see how things are going.
- We will also ask some parents to take part in an **extra 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 in any way.

- 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. You can also choose to withdraw **some or all of your information** from the study, but if you wish to do this you must tell us by the time the final assessment is due.

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 12 and the accompanying [Privacy Notice](#) for more details about how we **use your information** and **keep it safe**.



A CLOSER LOOK AT THE STUDY

Anxiety problems are among the most common mental health concerns in children.

- We have treatments that work well for child anxiety problems, but COVID-19 has brought challenges in how we deliver them.
- We don't know the best way to deliver treatment for child anxiety problems when there are social-distancing restrictions. To find out, we want to compare a new online treatment to the approach that your clinic is currently taking.

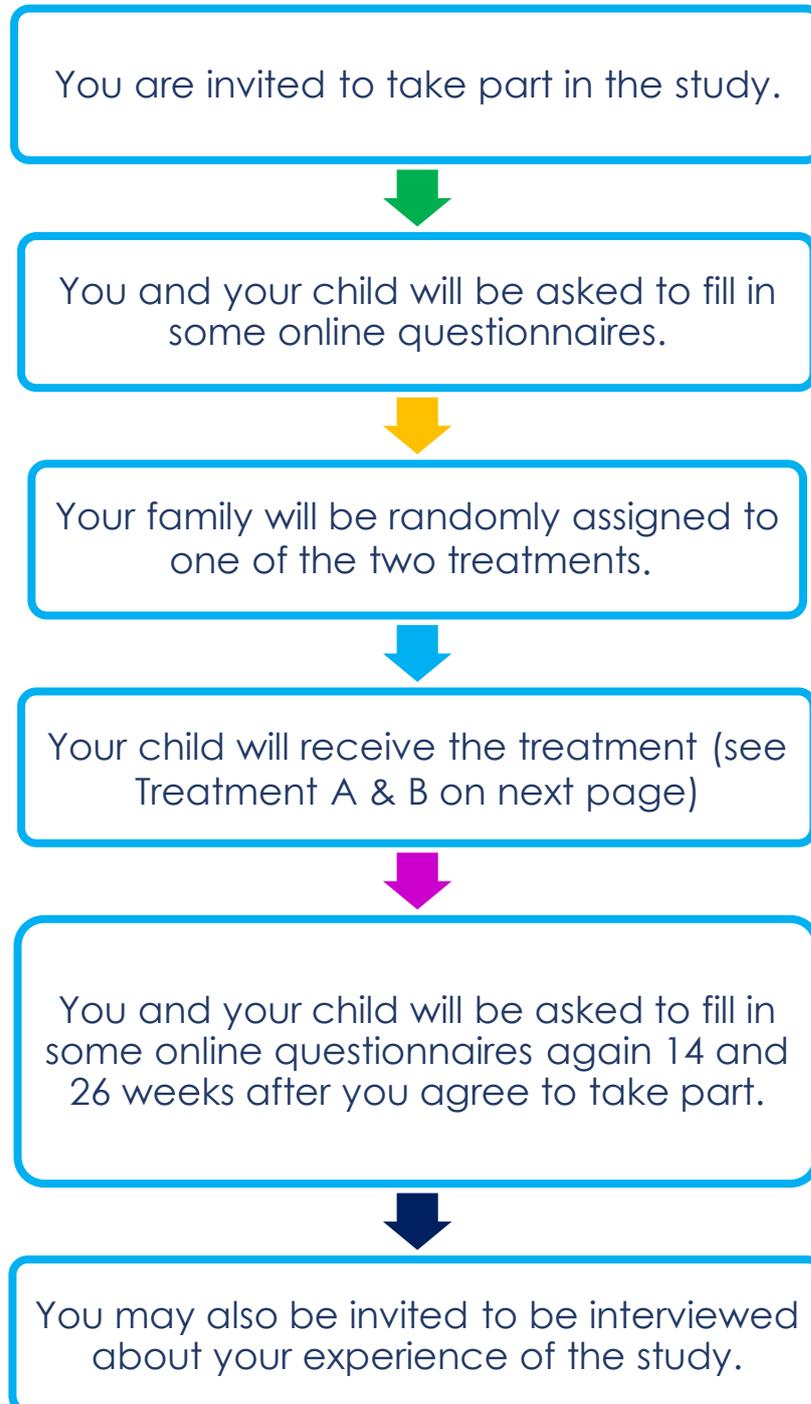
The aim of this study is to compare an online parent-led program with therapist support to treatment as usual:

- The new online platform involves 7 online modules which are accompanied by 7 weekly telephone calls for the parent/carer with a clinician
- Treatment as usual will be whatever your clinic currently offers to help children with anxiety problems.
- Families are put in the treatment group at random, using a computer programme.

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



What we will ask you and your child to do:



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



What happens in Treatment A and B?

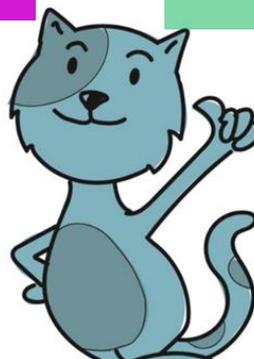
Treatment A

- access to a website with activities to work through with your child
- 7 sessions with you (the parent) over 7 weeks
- telephone sessions (15-20 minutes each)
- questionnaires to complete on the website
- final session at 11 weeks to check how things are going

Treatment B

(treatment as usual)

- the usual treatment currently being offered for child anxiety
- your child's therapist 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, mood, behaviour. You will also be asked some questions about your general lifestyle to provide some **general information** about your family. You can still take part in the study if your child agrees to take part in the study but does not want to complete the questionnaires.
- You will also be asked to **keep a diary** about the health-related appointments you and your child attend.
- You and your child's participation in the study is likely to last approximately **7 months** in total.
- We may ask you to take part in an **additional interview** after the treatment.

The additional 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 then be deleted as soon as they have been transcribed.)

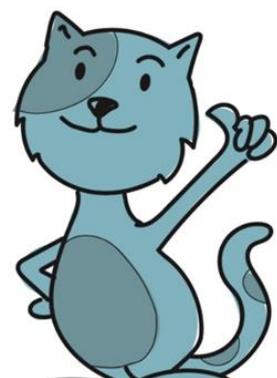


What are the advantages of taking part?

- We have good reason to think that most families who receive either therapy will **benefit**, but we don't know if one treatment will be better than the other or if they will be the same. That is why we are carrying out this research.
- By taking part, you and your child will be helping us to try to find the best way to **treat anxiety problems** in children in the COVID-19 context and we will learn a lot from this for the future.

Will I be reimbursed for taking part?

- **Each family will get £10** as a thank you for giving up their time to complete extra questionnaires.
- Parents who take part in the additional interview will receive a **further £20** as a thank you for their time.





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.
 - The questions are similar to the ones that are used in usual clinical practice and we work with families to make sure that the questions we ask are **as acceptable as possible**.

Other assurances:

- We don't foresee any harm coming to you or your child as a result of taking part in this study. All researchers have had criminal records 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 page 16).



How do we make sure your information is kept safe?

- 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.
- We will store the information you give us on a **secure University system**.
- None of this information will be taken out of the offices where we do the research and it will not be stored on personal computers.
- Only members of the research team will have access to personal information you give us.
- Both the files and the drive on which we store files are password controlled. Only members of the research team have access to these passwords.
- 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 others.
- If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.
- Information provided online will be on a **secure website**. Please see the [privacy notice](#) about how keep information we collect online safe.





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 the care your child receives from the NHS.
- If you do withdraw, you can also choose to withdraw some or all of your information from the study, but if you wish to do this you must tell us by the time the final assessment is due.

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.

Who is organising and funding the study?

This study is sponsored by the University of Oxford. It is funded by the **Department of Health and Social Care (DHSC)/UK Research and Innovation (UKRI) COVID-19 Rapid Response Initiative** (managed by the Medical Research Council).





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

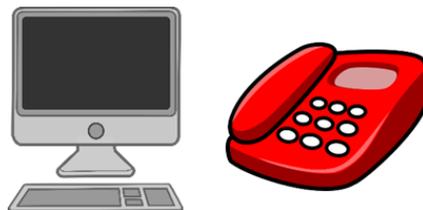
The online platform which delivers the online treatment was developed in collaboration with parents, children and therapists.

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 the London – City and East NHS Research Ethics Committee.

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 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:

- The University of Oxford has appropriate insurance in place in case you suffer any harm as a direct consequence of your participation in this study.
- 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 on page 16), or
- You may contact the **University of Oxford Clinical Trials and Research Governance (CTRG)** office on 01865 616480, or the head of CTRG, email ctr@admin.ox.ac.uk

The **Patient Advisory Liaison Service (PALS)** is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. Please contact the PALS team using following the link below <https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/>



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 also be provided a copy.
- We will also ask your **child to agree to take part** and fill out an online form for themselves.
- We will send a short letter to your child's GP letting them know that they are taking part.

If you don't want to take part:

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

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: Lucy Taylor
Email: cocat@psych.ox.ac.uk
Tel: 01865 271510



Chief Investigator: Cathy Creswell
Email: cathy.creswell@psych.ox.ac.uk

FUNDED BY

NIHR | National Institute
for Health Research

NIHR | Oxford Biomedical
Research Centre

NIHR | Applied Research Collaboration
Oxford and Thames Valley

THANK YOU!

For reading about our study

Co-CAT

Child Anxiety Treatment in the context of COVID-19



Department of Experimental Psychology

University of Oxford

Anna Watts Building

Radcliffe Observatory Quarter

Woodstock Road

Oxford

OX2 6GG

