Appendix A1: Participant Information Sheet



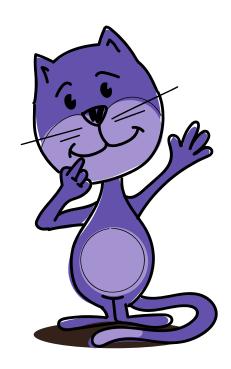




Minimising Young Children's Anxiety Through Schools

PARENT INFORMATION BOOKLET

Version 1.0 - 22.10.2020, Ethics ID R62531/RE001



What is MY-CATS?

MY-CATS – Minimising Young Children's Anxiety Through Schools – is a research project which aims to test a new way of identifying and supporting children to help build confidence and minimise problems with anxiety, now and in the future.

MY-CATS involves parents completing questionnaires to help us identify which children may be most likely to benefit from support, and then offering some of these parents online and telephone support. The support is designed to help parents encourage their child to build confidence and to provide them with skills and strategies for the future.

We would like your family to take part in MY-CATS.

But first, we will explain what the research is about. It is important that you understand what the research is about and what it involves. If you have any questions, please get in touch.

MY-CATS Team

Chief Investigator:



Professor Cathy Creswell **Trial Manager:**



Anna Placzek

University of Oxford

Department of Experimental Psychology, Anna Watts Building, Woodstock Road, Oxford

OX2 6GG

Website: www.osiresearch.org.uk/my-cats Email: mycats@psych.ox.ac.uk Telephone number: 01865 618614

Why has my family been invited to take part?

Your child's school has agreed to be involved in MY-CATS, and we asked your child's school to invite the families of all children in Reception, Year 1, and Year 2 to take part. We would like as many families as possible to be involved.

We are hoping about 5000 families from schools across England will take part.

What does taking part involve?

Part 1

1. CONSENT

We will ask if you agree to your family taking part. If you agree to take part, we will ask you to complete a consent form electronically.



2. SCREENING QUESTIONNAIRES

We will ask you to complete a short online questionnaire about how much your child experiences anxiety and shyness, and whether you experience any difficulties with anxiety. We will also ask you to provide some information about your family and your contact details so we can get in touch.



3. FEEDBACK AND TRIAL INVITATION

We will be in touch to let you know whether or not your responses indicate that you are eligible for the trial.

We are happy to discuss your responses with you over the telephone if you would like.

If you are eligible \rightarrow we will invite your family to take part in the trial and arrange a time to talk to you on the phone so we can tell you more about it and answer any questions.

If you are not eligible → we will provide you with some resources in case any concerns surrounding anxiety problems in your child crop up in the future.



Part 2

4. CONSENT AND BASELINE QUESTIONNAIRES

We will ask if you agree to your family taking part in the trial.

If you do agree to take part, we will ask you to complete the same online questionnaires you completed earlier on in the study, as well as some more questionnaires about you and your child.



5. RANDOMISATION

If you agree to take part in the trial, we will randomly allocate your school to one of two options.

A computer will determine which group your child's school will be in, and therefore which group you will be in.



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6. ONLINE AND TELEPHONE SUPPORT FOR PARENTS

You will be offered a parent-led, online support programme.
You can find a bit more information on what the programme involves on page 5.

6. USUAL SCHOOL PRACTICE

You will be offered a pdf version of the parent-led support programme at the end of the research project.



7. 6-WEEK & 12-WEEK QUESTIONNAIRES

We will ask you to complete some more online questionnaires about you and your child.



8. 12-MONTH INTERVIEW AND QUESTIONNAIRES

We will contact you directly to ask you to take part in an interview by telephone/video-call with a member of our research team.

During this interview, we will ask you a standard set of questions about anxiety your child may or may not be experiencing.

This interview normally takes about one hour.

To help us check the interviews are always carried out the same way, we will ask for your permission to make audio recordings of the interviews.

We will also ask you to complete some online questionnaires about you and your child.

FEEDBACK INTERVIEWS

Throughout different stages of the project, we will be asking a **subsample** of children and parents to take part in separate interviews to get feedback on the project and find out about families experiences of being involved. These interviews will be conducted over a video call or the telephone, and will last approximately one hour.

We will audio record these sessions to make sure we capture all of the discussion.

Online and telephone support for parents

The aim of the programme is to help children build confidence and help them learn to manage the everyday fears and worries that most children experience from time-to-time. By supporting parents to help their children, families will learn skills and strategies that they can use to minimise problems with anxiety, now and in the future.

The support programme involves:

- Access to a website with a series of 7 weekly modules, with activities to work through with your child. Each module takes about 30 minutes to complete.
- 7 weekly telephone sessions with a wellbeing practitioner, and a follow-up session about a month later (15-20 minutes each). We will ask for your permission to audiorecord these sessions to help us monitor how you are getting on with the programme and identify anything we can do differently to help you get the most out of the sessions.
- An optional child game designed to help motivate your child to face their fears

Does my family have to take part?

No. Your family do not have to take part in this research. You can choose whether you take part.

If you change your mind later, you can withdraw from the research at any time, without giving a reason. You can also choose to withdraw some or all of yours and your child's information from the study, but if you wish to do this, you must tell us before the end of the study.

What are the possible advantages and disadvantages of taking part?

Possible advantages

- Your family will be part of a large-scale, high profile research project to help build confidence in children at a young age so that they are less likely to have problems with anxiety in the future.
- If your family is eligible and happy to take part in the trial, we will offer you one of two options:
 - 1) Support via an online programme and sessions with a wellbeing practitioner during the trial, or
 - 2) Support via a pdf version of the programme that teaches the same skills and strategies at the end of the trial
- We have good reason to think that most families who complete the programme (either as online and telephone support or as a pdf version at the end of the trial) will benefit. We know from previous research that families often find it helpful to learn skills and strategies that they can use to help reduce children's problems with anxiety, now and in the future. This trial will help us to find the best way to teach these skills and strategies that is most helpful for families. We will offer some families support straight away (online with telephone support) and others will receive support later (via a pdf)- this will help us to find out more about how many families benefit from getting the support straight away. If your family is eligible and happy to take part in the trial, we will also provide you with a report of the detailed anxiety assessment that we conduct at the end of the study and information about sources of support. You can decide how many copies of the report you would like, and you will be free to share the report with school staff and other professionals/services.

To say thank you

We will offer families a £10 voucher after completing the questionnaires at the 6-week and 12-week follow-up and questionnaires and interview at the 12-month follow-up (up to £30 in total). We will also offer a £10 voucher to those families who take part in the interview to feed back their experiences of the project.

Possible disadvantages

You will need to spend some time completing the screening questionnaires (approximately 10 minutes). If you are eligible and willing to take part in the trial, you will also need to spend some time completing more questionnaires (approximately 30-40 minutes per timepoint), as well as taking part in interview (approximately 1 hour). You may also be asked to spend some time taking part in another interview about certain aspects of the project (approximately 1 hour).

We work with families to try to make sure the questions we ask are as acceptable as possible. But some of the questions we ask may address thoughts and feelings that may be upsetting. If the questions raise any concerns about yours and/or your child's mental health, there are people you can talk to for help or advice, including your GP and national organisations, such as Young Minds (www.youngminds.org.uk).

What happens to the information we provide?

All information we collect will be kept secure and in confidence. Please see below and the attached Privacy Notice (also available on our website www.osiresearch.org.uk/my-cats) for more information about how we keep your information safe.

- Your child will be given a unique ID number and we will use this to label all
 information we collect about your family. A document that links your/your child's
 name and contact details to your unique ID will be stored separately from all
 other information we hold about you. We will store this linking document until
 the analysis is complete and has been carefully checked.
- We will store screening questionnaire responses and responses to questionnaires in the main trial on a secure University server.
- Audio-recordings will be temporarily stored on audio-recorders, and once transferred to the secure University server, will be removed from audio-recorder.
 We will store audio-recording of feedback interviews until recordings have been transcribed and detailed analysis of transcriptions completed, and then safely destroyed. Audio-recordings of the interview about your child's anxiety and any audio-recordings of telephone sessions with the wellbeing practitioner will be

- stored for as long as needed to check the sessions are administed in a consistent way that is most helpful for families. This means that these audio-recordings will be safely destroyed by the end of the project.
- If you take part in the trial, with your permission, we will retain your contact details after the end of the project so that we can invite you to take part and input on future related studies. Once the research project is finished, we may release the project data for other researchers to use, but only in a way that makes it impossible for them to tell who has taken part.
- With your permission, we will let your child's school know whether your family were eligible for the trial.
 - *Schools like to know which children have been identified as more likely to benefit from support, so that they can put things in place to provide additional school support to the child if necessary*
- We will not share what you or your child tell us without your permission, unless
 you or your child chose to tell us something via telephone, email, letter, face-toface or on a questionnaire that made us think your child or someone else may be
 at risk of serious harm. If this happened, we may need to tell someone else about
 it, and we would always try to talk to you about it first.

Who is organising and funding the research project?

This study is sponsored by the University of Oxford. It is funded by Kavli Trust Programme on Health Research, which is committed to supporting research into child and adolescent mental health.





The project is organised by a team of researchers based at the University of Oxford, with support from researchers at other institutions, including the University of Exeter and the University of Reading.

What if I have a question or concern?

Contact the project team (telephone: 01865 618614; email: mycats@psych.ox.ac.uk), and we will do our best to answer any questions and deal with any concerns. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.

If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible.

Email: ethics@medsci.ox.ac.uk

Address: Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD.

Who has checked this research project?

This project has been checked by the University of Oxford Central University Research Ethics Committee.

All researchers working on the project have been subject to disclosure and barring checks and have been approved by the University of Oxford to work with children and families.

What should I do next?

Appendix A2: Participant Privacy Notice

MY-CATS Team

Chief Investigator:

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Trial Manager:

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MY-CATS: Minimising Young Children's Anxiety Through Schools Privacy Notice for parents/carers

Central University Research Ethics Committee (CUREC) Approval Reference: R62531/RE001

What is research data?

Research data is all the information we collect about you during research.

What is personal data?

Any research data that can identify you is personal data. This includes data that directly identifies you (e.g. name, audio recordings, email address), and also research data that could potentially reveal your identity if linked to other information (e.g. questionnaire responses labelled with a unique ID, and the ID is linked to your name elsewhere). Some more sensitive categories of personal data are known as **sensitive** (or **special category**) data (e.g. information about health, ethnicity).

Why do we collect, use and store your personal data?

For the purpose of research in the public interest.

Personal and sensitive data we collect helps us to understand and describe the research findings. We will also collect some personal data to allow us to contact you about the research.

What personal data will we ask you to give us to use in this study?



At the **screening stage**, we will ask you to give us the following personal data to help us understand and describe the research findings:

- Your child's month and year of birth, gender, ethnicity and whether they are eligible for free school meals
- Your age, relationship to your child, gender and ethnicity
- Your relationship status, household circumstances and housing tenure
- Information about your family and your/your partner's level of education and employment
- Information about the extent to which your child experiences anxiety and shyness, and whether you experience any difficulties with anxiety

We will ask you to provide the following personal information to allow us to contact you about your eligibility for the study:

- Your child's name, your child's school name and year group
- Your name, address, telephone number, postcode and email address

If you are **eligible for the study** and happy to take part, we will also ask you to give us the following personal data to help us understand and describe the research findings:

- Any changes to your relationship status, household circumstances and housing tenure
- Information about your family and your/your partner's: employment and income
- Information about your child's fears and worries, thoughts, feelings, behaviour
- Information about yours and your child's health and use of services, and your relationship with your child and general lifestyle
- If you take part in the online and telephone support, we will ask to make audio-recordings of feedback and telephone sessions with a wellbeing practitioner. If you and/or your child take part in an interview about your experiences of taking part in this research, we will also ask to make audio-recordings of these sessions.

How will we keep your personal data safe?

- Personal data will be collected from you and your child using a secure website, with end-to-end encryption, and using audio-recorders if applicable
- Families who take part in the online and telephone support will be provided with more information about how we keep your personal data in this part of the research safe.
- We will share some information we collect from families with researchers in the
 wider project team at the University of Reading and University of Exeter so they can
 help with analysing the data, but this will not include any information that could

reveal your identify. Responsible members of the University of Oxford may also need to see the information we collect from families for data monitoring and auditing purposes.

- Audio recordings will be temporarily stored on audio-recorder devices, and once transferred to a secure server, they will be permanently deleted from audiorecorders.
- We will transcribe feedback interviews, and will not include any information that could reveal your identity in transcriptions. We will use an external transcriber who has been approved to work with the University of Oxford and has signed a confidentiality agreement.
- Your personal information will be stored under a unique ID. We will have a
 document that links your/your child's name and contact details to your unique ID
 and we will store this document separately from all other information we hold about
 you. All other information we collect about you and your family will be labelled with
 this unique ID. Files with audio-recordings will be labelled using your unique ID and
 will be stored separately from all other information we hold about you.
- Any data or findings from the research that is published will not identify you or your child. We may use direct quotes from interviews or discussion groups in publications, but this will not include any information that could identify you or your family.

How long will we store your personal data?

We will only store your personal information for as long as it is required for research purposes and appropriate safe-guards are in place.

- 1. Consent forms: these will be stored for a minimum of 3 years after the end of the research project.
- 2. Audio-recordings of feedback interviews will be stored until recordings have been transcribed, transcriptions thoroughly checked, and detailed analysis is complete.
- 3. Audio-recordings of interviews about your child's anxiety and telephone sessions with the wellbeing practitioner will be stored for as long as needed to check the sessions are administed in a consistent way that is most helpful for families. This means that these audio-recordings will be safely destroyed by the end of the project.
- 4. If you take part in the trial, with your permission, we will retain your contact details after the end of the project so that we can invite you to take part and input on future related studies.
- 5. Families who take part in the online and telephone support will be granted access to the website for at least 12-months, and all personal data collected via the online support programme will be stored for as long as a parent/carer retains access to the online programme. Families who are offered the online and telephone support will be provided with more information about how long we store your personal data. The document that

links yours/your child's name to other information we collect about you will be stored until all data collection is complete, all data and information has been carefully checked and the main analysis is complete, and then permanently deleted. Beyond this point, other research data we hold, including responses to screening questionnaires, will not include any information that could directly identify you or your family.

If you withdraw from the research after data collection is complete, we may continue to use and store information that you provided for the purpose of the research. This information would not include anything that could directly identify you or your family.

Who is responsible for protecting your personal information?

The University of Oxford is responsible for protecting your personal data (the 'Data Controller').

Who should I contact if I have concerns about data protection or my rights?

data.protection@admin.ox.ac.uk

What are your rights under data protection law?

You have certain rights under data protection law which are to:

- Withdraw your consent
- Access your personal data or ask for a copy
- Rectify inaccuracies in personal data that we hold about you
- Be forgotten, (i.e. your details to be removed from systems that we use to process your personal data)
- Restrict uses of your data
- Object to uses of your data, e.g. retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your individual rights on the University of Oxford website at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/ and on the website of the Information Commissioners Office (ICO) at https://ico.org.uk.

You also have a right to complain the ICO if you are unhappy with how your data has been handled.