

INFORMATION SHEET FOR PARENTS

REC Reference Number: HR 16/17-3058

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Investigating anxiety in young people with and without autism spectrum disorders

I would like to invite you and your child to take part in a new research project that is part of my PhD research at the Institute of Psychiatry, Psychology and Neuroscience, King's College London (KCL). Participation in the research study is voluntary and your child should only participate if you would both like to be involved. If you choose not to take part in the research study this will not disadvantage you or your child in anyway. Before you decide whether you both would like to take part, it is important to read through this information sheet carefully. This will help you understand why this research is being done and what you and your child's participation will involve. Please take time to read this sheet and discuss with others if you wish. Please do not hesitate to contact the research team if there is anything that is not clear or if you would like any more information.

What is the purpose of the study?

This study aims to understand how anxiety develops in young people with and without a diagnosis of autism spectrum disorder. We are specifically interested in answering two key research aims. Firstly, we are interested in whether anxiety develops for the same reasons in young people with and without autism. Secondly, we are interested in exploring any differences in how and why anxiety develops in young people with and without autism. This research is important for understanding what causes anxiety in young people, which will allow us to develop better interventions to target these symptoms.

Why has my child been invited to take part?

You have been invited because your child is between 12 and 18 years old and your child's school have expressed that you might be interested in taking part. We have also invited children with and without a diagnosis of autism from this organisation, other schools and parent support groups.

Who must we exclude?

We must exclude any children who suffer from epilepsy, any genetic disorder or psychotic disorder. We must also exclude children who do not have fluent English. We will check with you or your child's school for documentation confirming their autism spectrum disorder diagnosis.

Where will the study take place and how long will it last?

The study will take place in a quiet room at your child's school. If this is not a suitable option for you, then there will be an opportunity for yourself and your child to take part in our research in a room at a KCL Research centre, at Denmark Hill, SE5 8AF. Home visits will also be available if your child is unable to attend a session at school or in a KCL Research centre. You do not need to come along for the school sessions, however, for sessions at the KCL Research centre you should come along with your child.

The study will take around 3 and a half hours to complete. Your child can take part in any number of sessions to complete the study. Your child's first session will be 45 minutes. For all other sessions you or your school can choose the duration, however, the minimum session duration is 30 minutes. All sessions will take place within a month of each other. All school sessions and home visits will take place on weekdays. All sessions at the KCL Research centre will take place on weekdays and weekends. All sessions will be carried out within standard office hours. For a visual guide please see the study flowchart within this form.

What will your child be asked to do?

In the first session, your child will be asked to complete some puzzles and language tasks with the researcher. These measures are used to screen all children for eligibility in the study. After the first session we will contact you to let you know whether your child is eligible to take part in the rest of the study. If your child is not eligible, we will still contact you to let you know and they won't be asked to complete any further sessions. If your child is eligible, then we will arrange some more sessions and they will be asked to take part in the measures described below.

Fill in questionnaires: Your child will be asked to fill in several questionnaires on the computer. Some of these questionnaires will ask your child about situations they may worry about. Your child will also be asked to say how often they feel certain emotions and how they react to these. Some questions will ask your child about feelings in their body. Other questionnaires will ask your child about how they look at their environments and any difficulties they may experience.

Interactive tasks: In one task your child will be asked to watch and describe what is happening in some animated video clips. In a second task your child will be asked to answer some questions after listening to two short stories. In another task your child will be asked to listen to their heart.

Semi structured interview: Your child will be asked to think about some experiences that may have made them feel happy, anxious or worried. They will also answer some questions about how they felt.

None of these tasks or questionnaires are a test and there are no right or wrong answers.

What will you be asked to do?

As the child's caregiver, you will be asked to fill out some online questionnaires. They will take approximately 30 minutes to fill out. These will be sent out after your child's first session and should be completed before your child's second session. The questionnaires can be filled out at any time in this period that is best for you.

Online questionnaires: You will be asked to complete four online questionnaires. Some of these questionnaires will ask you about your child's emotions and behaviours. Another questionnaire will measure how your child acts in different situations.

What if I don't want to take part anymore?

If at any point you or your child do not wish to continue with the research project, please tell the researcher and they can stop all future sessions. You can withdraw from the project, without giving any reason and all identifiable data will be destroyed. You can withdraw from the study at any point up until 31st December 2018.

What are the benefits if your child takes part?

Taking part in this study will help create better interventions for anxiety in young people with autism. As a sign of our appreciation for completing all sessions, your child will be entered into a prize draw for a chance to win one of three gift cards (£200, £100 or £50). Your child will be given 5 raffle tickets for the prize draw and a small gift if they take part in all sessions. The winners will be chosen after the study is complete and the gift card will be sent to you in the post. If you withdraw from the study early or if your child is not eligible to take part after the first session they will be given less raffle tickets for the prize draw.

What are the risks if your child takes part?

The risks involved in this study are small. Your child will be asked to answer some questions and think about some experiences that may make them feel uneasy. There will always be a researcher with your child and they will be allowed to stop the study at anytime, without giving a reason. Your child will be given plenty of breaks in each session to reduce any potential risks, and where possible fun games will be offered to play in the breaks. If your child displays any distress at school, a system for getting teacher support will be put in place.

Will my taking part be kept confidential?

Everything you and your child tell us will be kept completely confidential following the limits of the law. If you give consent for your child to take part in the study, you and your child will be given a unique identification (ID) number and any responses will only be linked to this ID number. This will ensure that all information is anonymised, with the exception of the consent form and your child's documentation of diagnosis, which will contain both your child's personal information and ID number. These documents will be securely stored in a file safe that will be kept in a locked draw away from any unidentifiable data that contains your unique ID number.

Any information that is collected in pencil and paper format will be kept under lock and key at the researcher's place of work. All electronic data, including questionnaires filled out by you and your child, will be kept in an encrypted file on a password protected computer using only the unique ID number. All audio-recorded data will be transcribed and files will be transferred to an encrypted file on a password protected computer.

Both you and your child's responses will remain confidential unless either of you bring to the researchers attention anything to suggest that your health and safety is currently in danger (e.g. extreme distress or abuse). If this happens, information directly related to the emergency will be brought to the attention of the appropriate bodies.

What will happen to the results of the study?

The results of this study will be collated into the researchers PhD thesis. The research findings will also be submitted for publication and presented at conferences worldwide.

What if I have further questions about the project?

If you have any questions or require more information about this study, please contact Hannah Pickard by email at hannah.pickard@kcl.ac.uk, or by telephone on: 07397002034 or by post at room C3.16, PO80, SGDP Research Centre, King's College London, 16 De Crespigny Park, London, SE5 8 AF. If this study has harmed you or your child in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London for further advice and information. This research project is led by Professor Francesca Happé, director of the Social, Genetic and Developmental Psychiatry centre: <https://kclpure.kcl.ac.uk/portal/francesca.happe.html>. She can be contacted by email at francesca.happe@kcl.ac.uk, or by phone at +44 20 7848 0871.

What do I do if I want my child to take part?

If you would like your child to take part in the study you will be asked to sign the consent form, which is attached to this information pack. By signing this consent form you are **agreeing** that both you and your child are happy to take part in the study. It is **important** that you read through this information sheet and sign the consent form before filling out the attached questionnaires. Once you have signed and completed all forms please post these back to the research team to confirm that your child would like to take part in the study. You will be able to keep the information sheet to refer back to for study information and contact details. When we have received your signed consent forms and questionnaires you will be contacted to organise your child's first session.

Study flowchart

