

Parents and Young Children under Extreme Stress Information Sheet for Children 6-8

What is a research study?

You do a research study when you want to learn about something or find out something new.

Why is this study being done?

We are doing this study (called PYCES2) to find out if we have a good way of helping children who have been in a frightening event. This way of helping children is called "trauma focused cognitive behavioural therapy" or TF-CBT for short.

Do we have to take part?

No, it is up to you and your family to decide!

If you change your mind and want to stop taking part at any point, that is also fine. You don't even have to tell us why. You will not be treated any differently by doctors or other people helping you if you decide not to take part.

Who is taking part?

We are asking about 80 children who have been in a frightening event to take part in this study.

What will happen if I say yes?

First, we will ask you to play some games and answer some questions that help us to understand how you are feeling. This will take about half an hour.

We will also talk to your parent(s) about what happened and how things have been for you since then. Your parent(s) will answer some questions on the computer, and everything together will take about 2 hours. The questions help us understand how you have been feeling. Sometimes we may ask you to do small activities or practise things at home between sessions.

After this, you will either have the treatment called TF-CBT, with us for 12 weeks, or you will carry on being looked after by your GP or doctor. After the first meeting, a computer will choose which group you are in. This is done by chance, like flipping a coin, so that we can fairly compare different ways of helping children.

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After 6 weeks, 12 weeks, and again a few months later, we will ask you and your parent(s) more questions to see how you are feeling and thinking.

What happens during the treatment?

We will meet with you and your parent(s) once a week for about 12 weeks. Your parent or carer will be with you during your sessions to help support you, and each visit will last about one and a half hours. The study is organised by a research team in Cambridge, but you will meet with your therapist at a place near where you live, such as a local NHS clinic or your home. You will not need to travel to Cambridge. We will talk about the frightening event that happened to you and how it made you feel. We would also talk about how you can learn to feel better. Sometimes, children say that at first it can be upsetting to talk about a frightening event like this. But we think that most children find that after talking about it, they feel a little bit better. If you ever feel upset during the sessions, you can tell us and we will help you feel safe and comfortable.

Who is running this study?

The study is run by doctors and researchers from the NHS and universities.

Who will know I am taking part in this study?

We will let your GP (family doctor) know that you are helping with this study, and when the study is finished, we will send your family a short summary of what we found, written in a way that is easy to understand.

No one else will know you are taking part, and we won't tell anyone what you say. We will not share your name or address with other people.

We will keep all the information you and your parent(s) give us very safe, using special computers that only the research team can use. If we share any findings from the study to help other children in the future, we will make sure that no one can tell the information came from you.

We will keep your answers and other information safe for 20 years after the study, which is what the rules say we must do.

Your information will be looked after by the NHS and the University of Cambridge following UK data protection laws.



Has this research study been checked by an ethics committee?

Yes, this study has been checked by the NRES Committee East of England - Cambridge South Research Ethics Committee (Study reference: 26/EE/0048).

These people check our study to make sure it is safe for us to do our research and for you to take part.

I have some questions about this study, who do I contact?

Your parent(s) or carer have also got lots of information about the study. If you have more questions, you can speak to Alicja Podgorski, who is running this study.

Her address and contact details are:

Address: MRC Cognition and Brain Sciences Unit,
15 Chaucer Road, Cambridge, CB2 7EF

Direct line: 01223 769906

Email: alicja.podgorski@mrc-cbu.cam.ac.uk

Website: <https://c2ad.mrc-cbu.cam.ac.uk>

Thank you very much for reading this information sheet about the PYCES2 study - we hope you decide to take part in this study!

