



## Parents and Young Children under Extreme Stress: Information Sheet for Parents

We are carrying out the PYCES2 study to investigate the effectiveness of our treatment for post-traumatic stress disorder (PTSD) in young children. We would like to invite you and your child to participate in the PYCES2 study. This information sheet was prepared to help you decide if you wish for you and your child to participate. Your participation is *entirely voluntary*.

### What is the purpose of the study?

There are currently no effective treatments for young children suffering from post-traumatic stress following traumatic events. Our team of researchers and clinicians have developed a psychological treatment for PTSD in young children. We are running the PYCES2 study to test the treatment's effectiveness. We have already completed one study (PYCES) that showed that our treatment was acceptable to the parents, children and clinicians taking part. This study also provided early evidence that the treatment was effective in treating PTSD in young children. We are now running another study (PYCES2) to further test the treatment's effectiveness. This study can benefit many children who struggle after having been exposed to a traumatic event.

### Why have we been invited to take part?

You have been invited to take part in the PYCES2 study as your child has recently been through a frightening event and may be experiencing the distressing symptoms of PTSD. We are inviting 80 such children to participate in the PYCES2 study.

### Do we have to take part?

No, it is up to you and your child to decide. If you do want to take part, we'll ask you to sign a consent form, a copy of which you can keep with this information sheet. Both you and your child are free to withdraw from the study at any point *without giving us a reason*. You will not be treated any differently by any NHS service if you decide not to participate in this study or if you decide to withdraw at any time during the study.

### What treatment for PTSD are you testing?

We are testing a psychological treatment (i.e. no medication or drugs are involved) called "trauma-focused cognitive behaviour therapy". This treatment is now thought to be the best treatment for adults, and there is good evidence that it is effective for older children and teenagers with PTSD as well. We would like to know how well it works for younger children after a frightening experience. The treatment would last for up to 12 weeks, and we would like to see you and your child each week at the same time for about 1½ hours. The treatment involves remembering and talking about

the traumatic event, and learning how to cope. This can sometimes be upsetting for children at first, but we believe that it will help a great deal in the long term.

### **We would like to take part – what happens now?**

Initially, you and your child will have an assessment with one of our clinicians or researchers. This will take place in person at one of our clinics, at your home or over the phone. This will involve interviews and questionnaires. After this, your child will be assigned to either: i) our treatment for PTSD, a version of cognitive behavioural therapy (CBT) that is called trauma focused cognitive behavioural therapy (TF-CBT), which lasts for approximately 12 weeks, or ii) a 12-week period where they would receive care as usual. This means that you and your child would continue to receive any care you would normally get from your GP or CAMHS (Children and Adolescent Mental Health Services), and would not receive our treatment for PTSD.

Whether or not you and your child are allocated to the treatment is *entirely random*. The reason for not providing the treatment to everyone that takes part in the study is so that we can compare children who receive our treatment to children who receive normal NHS care, to see who is doing better.

We will record the treatment sessions using a video or audio recording device. This is to help us ensure that we are delivering the treatment in the best possible way. These recordings will be stored in a secure location and destroyed within 5 years of the study being completed.

We will also re-assess you and your child in the middle of the study (after approximately six weeks), at the end of the treatment (at 12 weeks) and three months later, using the same interviews and questionnaires as before. This is so we know whether any improvements from the treatment are long-lasting.

### **Who is running this study?**

This study is being run by researchers and clinical psychologists at the University of Cambridge, University of East Anglia and King's College London, in collaboration with Cambridge and Peterborough NHS Foundation Trust, South London and Maudsley NHS Foundation Trust, and Norfolk and Suffolk NHS Foundation Trust. We have psychologists based in Cambridge and London and will arrange to see your child at a place that is convenient.

All the information we collect about you and your child will be stored securely and analysed by psychologists at the Medical Research Council Cognition and Brain Sciences Unit, University of Cambridge.

### **Confidentiality – who will know we are taking part in this study?**

All information collected about you and your child during the research will be kept strictly confidential. Members of the research team will analyse the information, and they will only contact you if you have given permission. We may share anonymous data with other researchers to help further our understanding in this area, but they would not be able to identify or contact you or your child.

The results of the study may be published in to support other professionals working with children who have experienced frightening events. However, you or your child would *not* be named or identifiable in any publications.

With your permission, we will also inform your GP that your child is taking part in this study.

**How will our information be kept safe?**

Your personal information will be stored securely and handled in line with UK data protection laws. Only the research team and authorised monitors will have access to it, and all data will be kept private and protected throughout the study.

**Will we receive anything as a thank you for helping with this research?**

Yes, to thank you for your time you will receive £30 at the first visit and at each visit after the end of treatment. You can share this with your child as you see fit.

**What happens if we withdraw from the study?**

You are free to withdraw from the study at any point, without giving us a reason. If you withdraw from the study, it is up to you whether we use any of the information we have already collected; if you wish, we will destroy this.

**Has this research study been approved by an ethics committee?**

Yes, this study has been reviewed and approved by the NRES Committee East of England – Cambridge South Research Ethics Committee (Study reference: XXXXXX).

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

You can contact Alicja Podgorski at the MRC Cognition and Brain Sciences Unit, who is the Clinical Trial Lead and Research Therapist 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](mailto:alicja.podgorski@mrc-cbu.cam.ac.uk)  
Website: <https://c2ad.mrc-cbu.cam.ac.uk/>

**What if I am not happy about the research study or wish to make a complaint?**

If you are not happy about this research study or wish to make a complaint about it, then please contact Prof Tim Dalgleish ([tim.dalgleish@mrc-cbu.cam.ac.uk](mailto:tim.dalgleish@mrc-cbu.cam.ac.uk), direct line 01223 767654) or the NHS Patient Advisory Liaison Service at Addenbrooke's Hospital ([pals@addenbrookes.nhs.uk](mailto:pals@addenbrookes.nhs.uk), 01223 216 756).

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