



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

We are carrying out the PYCES 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 PYCES 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*.

### **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 PYCES study to 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 PYCES study as your child has recently been through a frightening event and may be experiencing the distressing symptoms of PTSD. We are inviting 60 such children to participate in the PYCES study.

### **Do we have to take part?**

No, it is up to you and your child to decide. If you do want to join in 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 chronic PTSD as well. We would like to know how well it works for younger children after a frightening experience. The treatment would last for 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 at our clinic. 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 12 weeks, or ii) a 12-week waiting period. After the waiting period children can then receive the TF-CBT treatment if they still need it. At the end of the treatment or the waiting period your child will be re-assessed, using the same interviews and questionnaires as before.

Whether or not you are asked to come for treatment straight away or after a delay is *entirely random*. The reason for asking some people to wait before having treatment is so that we can compare children who were treated first with those who waited first, to see who is doing better.

We will record our 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.

As part of the PYCES study we are also looking at whether certain genes affect how children cope with being involved in a frightening event. We can measure genes from saliva (spit). If you and your child consent to us collecting a saliva sample, then we will do so when you come for assessment. You can choose not to give a spit sample – this will not affect your chances of being included in the study.

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

The study is a joint project between East Anglia emergency departments, the Medical Research Council Cognition and Brain Sciences Unit, and the University of Cambridge. All the information we collect will be stored and analysed by psychologists at the Medical Research Council Cognition and Brain Sciences Unit. The trial is being run at the Herchel Smith Building, which is next to Addenbrooke's Hospital but we would be able to arrange to see you and your child nearer to your home if this is not convenient.

### **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. Information will only be analysed by members of our research team, and they will only be able to contact you if you give them permission to do so.

The results we obtain may be published in order to help other people working with children who have been in frightening events, but you or your child would *not* be named and would not be identifiable in these publications.

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

### **What will happen to any DNA (saliva) samples my child gives? Will any genetic tests be done?**

Saliva samples will not have names on them, only an identification code. We would like to store the part of the saliva that contains their genes (DNA) after the study, in case future research tells us that we should test it for other genes. It is up to you whether we store this DNA after the study and we shall only do this if you give us specific permission on the consent form. If you do not want us to do this, we shall destroy your child's samples after the study. We would need separate permission from an ethics committee to carry out these additional tests after the study.

Please note that the genetic testing done as part of this study is NOT done for diagnostic purposes. We are therefore unable to provide you with any information about your child's sample.

**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?**

If you withdraw from the study it is up to you whether we use any information we have already collected or your child's saliva sample; if you wish, these will be destroyed.

**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: 12-EE-0458).

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

You can contact Dr Ben Goodall at the MRC Cognition and Brain Sciences Unit, who is the Clinical Psychologist running this study.

His address and contact details are:

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

Direct line: 01223 760 673

Email: [ben.goodall@mrc-cbu.cam.ac.uk](mailto:ben.goodall@mrc-cbu.cam.ac.uk)

Website: [www.pyces.org](http://www.pyces.org)

**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 273 685) 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 PYCES study - we hope you decide to take part in this study.**