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 this 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 is currently limited evidence for effective treatments for young children suffering from post-traumatic stress following traumatic events. Our team of researchers and clinicians from 3 centres (Cambridge, Norfolk, and South-East London) 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 and it will also form part of a PhD research project at the University of Cambridge. 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. If you and your child are assigned to be treated, 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

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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 your local participating NHS site, at your home, or over the phone where appropriate. The initial assessment will consist of some online and in-person questionnaires and take approximately 2 hours. If you are unable to access online systems, alternative options are available, including paper questionnaires or completing them with support from a member of the research team (in person or by telephone or video call). After this, your child will be assigned to either: a) 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 b) 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. Follow-up assessments (mid-treatment, post-treatment, and 3-month follow-up) will take approximately the same amount of time. The researchers carrying out the assessments will not know which group your child has been assigned to. Parents/carers will attend all treatment sessions alongside their child as an integral part of the CBT-3M intervention. This allows parents to support their child during sessions and to help practise strategies between sessions. During the treatment period, you and your child may also be asked to complete brief activities or practise tasks at home between sessions. If your child becomes distressed during sessions, the clinician will support them and ensure they feel safe. At the end of the study, participating families will receive a summary of the main findings in accessible language.

Whether or not you and your child are allocated to the treatment is *entirely random* – this means a computer will decide by chance. 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 secure audio or video recording device. These recordings will be stored on encrypted, password-protected systems and only accessed by authorised members of the research team for the purposes of supervision and ensuring the quality of the treatment. Recordings will be stored securely and deleted after an appropriate retention period in line with study policies. Recordings will not be used for any other purpose without your explicit consent.

We will also re-assess you and your child in the middle (at 6 weeks) and 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 coordinated by the research team based at the University of Cambridge. Following initial screening and allocation, participants will be seen by clinical psychologists from their local participating NHS site (for example, at South

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London and Maudsley NHS Foundation Trust for families in London). Participants will not be required to travel to Cambridge for treatment. We will arrange to see your child at a location that is convenient for you.

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

How will we use information about you?
The University of Cambridge and Cambridgeshire and Peterborough NHS Foundation Trust are the joint sponsors for this study. They will be using information from you and your child in order to undertake this study and will act as the data controllers for this study. This means they are responsible for looking after your information and using it properly.

We will need to use information from you and your child for this research project. This information will include your child's name, NHS number and contact details, and information from their medical records.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you and your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will keep this data for 20 years, after which it will be securely destroyed.

We will write our reports in a way that no one can work out that you or your child took part in the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you and your child that we have already collected.

The University of Cambridge and Cambridgeshire and Peterborough NHS Foundation Trust will keep identifiable information about you and your child for 20 years.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dpo@cpft.nhs.uk (the Data Protection Officer for Cambridgeshire and Peterborough NHS Foundation Trust)

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

Parents will receive a £30 reimbursement to help cover travel and other expenses associated with attending research assessments. This reimbursement is not dependent on completing treatment.

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.

What if something goes wrong?
The University of Cambridge and the participating NHS organisations have appropriate insurance and indemnity arrangements in place for this study.

If you are harmed due to someone's negligence, you may have grounds for legal action for compensation against the responsible organisation. If you are harmed as a result of taking part in this study but this is not due to negligence, the University of Cambridge has arrangements in place to consider compensation on a case-by-case basis.

If you would like more information about insurance and indemnity arrangements, please contact the research team using the details provided at the end of this information sheet.

Has this research study been approved by an ethics committee?
Yes, this study has been reviewed and approved by the Cambridge South Research Ethics Committee (Study reference: 26/EE/0048).

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

With your permission, we may contact you in the future about other research studies.

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, direct line 01223 767654) or the NHS Patient Advisory Liaison Service at Addenbrooke's Hospital (pals@addenbrookes.nhs.uk, 01223 216 756).

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

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