



## **ASPECTS: Acute Stress Programme for Children and Teenagers**

We are carrying out the ASPECTS study to see how effective our treatment of post-traumatic stress disorder (PTSD) in children and teenagers is. The ASPECTS study is focused on trying to treat PTSD quite soon after a frightening experience (about three months). We would like to invite you and your child to participate in the ASPECTS study. Please read this information sheet if you wish for you and your child to participate. Your participation is *entirely voluntary*.

### ***Purpose of the study:***

We have a psychological treatment for PTSD in young people that is effective, but we don't know how good the treatment is quite soon after a frightening experience. We would like to test whether it is still a good treatment at this early stage. The advantage of having good early treatment for PTSD in young people is that we can help them to get back to doing well at school, with their friends etc, as soon as possible, before the PTSD can become chronic and impact on their lives in a bigger way.

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

You have been invited to take part in the ASPECTS study as your child has recently been through a frightening event and may be experiencing the distressing symptoms of PTSD. We hope to recruit 60 children and teenagers into this trial.

### **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 choose not to participate in this study or if you decide to withdraw.

### **What treatment for PTSD are you testing?**

We are testing a psychological treatment (i.e. no medication or drugs are involved) called "cognitive behaviour therapy" or CBT. This treatment is now thought to be the best treatment for adults, and there is good evidence that it is effective for children and teenagers with chronic PTSD as well. We would like to know how well it works for children and teenagers quite soon after a frightening experience. The treatment would last for 10 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 and teenagers 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, and completing some experiments. After this, children and teenagers taking part in the ASPECTS trial will be assigned to either: i) our treatment for PTSD, called cognitive behavioural therapy (CBT), which lasts for 10 weeks, or ii) a 10-week waiting period. After the waiting period children will be offered the 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, questionnaires and experiments 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 with those who were not treated, 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.

### **Why are you doing experiments and what will they involve?**

We are doing several experiments as part of this trial. By doing these experiments before and after the treatment or waiting period we hope to understand much more about which psychological and biological factors *cause* PTSD in children and teenagers, and what things help them to recover afterwards.

The experiments will involve three things. First, your child will be asked to describe the event they have experienced, and two other events (one positive and one negative). We will record these descriptions using a video or audio recording device.

Second, they will be asked to try to do a mentally demanding task, while trying to ignore other pieces of information. Some of this distracting information will be to do with the event your child went through. This is meant to simulate the kinds of thoughts and memories that children and teenagers with PTSD frequently experience and have to cope with.

Third, your child will complete some short intelligence and memory tests.

We would also like you to fill in a short questionnaire.

These tests and questions will last for about 2 hours, but you can have breaks during them. As these experiments are not part of a normal clinical assessment, we will pay you £30 (to be given to your child as you feel appropriate) for their time in completing these additional tasks. This is on top of any payment you might have received earlier from us. This payment is to cover travel costs, but we can also pay for additional travel expenses if you have come a long way.

We are also looking at whether certain genes affect how children and teenagers cope with being involved in a frightening event. We can measure genes from saliva (spit) – we do not need to do blood tests. If your child has not already given us a saliva sample we collect one when you come for assessment. You can choose not to give a spit sample if you do not wish to do this part of the research.

We will also ask your child to provide several spit samples on the day you come to our research clinic. These samples will be used to measure the presence of stress hormones.

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

The study is a joint project between Addenbrooke's hospital, 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 Hershel Smith Building, which is next to Addenbrooke's Hospital.

### **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 Medical Research Council Cognition and Brain Sciences Unit, 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.

We will inform your GP that you child is taking part in this study.

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

Saliva samples will not have names on them, only an identification code. We'll ask you to post their saliva to our office, where they will be stored in a freezer and then taken (without names on) to a laboratory.

We would like to test your child's saliva for some genes that we think may affect how they cope after a frightening experience. 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. We will identify genes that affect the levels of serotonin and dopamine in the brain. These are natural chemicals in the brain and are thought to be involved in our mood. We will not tell anyone else about the results of these genetic tests.

***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 approved by Cambridgeshire 1 Research Ethics Committee (Study No. 10/H0304/11).

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

You can contact Dr Richard Meiser-Stedman at the MRC Cognition and Brain Sciences Unit who is over-seeing this project. His address and contact details are:

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

Direct line: 01223 273624

Email: richard.meiser-stedman@mrc-cbu.cam.ac.uk

Website: [www.aspects-study.org](http://www.aspects-study.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 Dr Richard Meiser-Stedman (see contact details above), the NHS Patient Advisory Liaison Service at Addenbrooke's Hospital (01223 216 756, [pals@addenbrookes.nhs.uk](mailto:pals@addenbrookes.nhs.uk)), or Dr Tim Dalgleish, Senior Scientist at the MRC Cognition and Brian Sciences Unit (01223 273685, [tim.dalgleish@mrc-cbu.cam.ac.uk](mailto:tim.dalgleish@mrc-cbu.cam.ac.uk)).

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