



ASPECTS: Acute Stress Programme for Children and Teenagers

Sometimes young people who go through frightening experiences can have some very anxious feelings afterwards that do not go away on their own. These anxious feelings are sometimes called post-traumatic stress disorder or PTSD. The ASPECTS study is about trying to treat these feelings quite soon after a frightening experience. We would like you to take part. Please read this information sheet if you are interested in taking part. Your participation is *entirely voluntary* – it's completely up to you.

Purpose of the study:

We have a treatment for helping the anxious feelings that young people can have after a frightening event. This treatment is based on talking, not drugs or medication. But we don't know how good the programme is quite soon after a frightening experience. We would like to test whether it is still a good treatment quite soon after a frightening event.

Why have we been invited to take part?

You have been invited to take part in the ASPECTS study as you recently had a frightening thing happen to you. 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 family. You are free to stop taking part in the study any time you like. If you don't want to take part in the study or decide to stop taking part in the study you will not be treated any differently by a hospital or your doctor.

What treatment for PTSD are you testing?

The treatment is called "cognitive behavioural therapy" or CBT. For CBT, we would like to see you once a week, for 10 weeks, for about an hour and a half each time. We would talk about the accident, and how you have been feeling since it happened, and how you can learn to feel better. Sometimes, children and teenagers say that at first it can be upsetting to remember the accident like this. But we think that most children find that it helps to talk about the accident.

I would like to take part – what happens now?

Initially, you will have an assessment at our clinic. This will involve answering some questions, filling in some questionnaires, and doing some special tests called experiments. After this, children and teenagers taking part in the ASPECTS trial will be either given: i) our treatment for PTSD, CBT, which lasts for 10 weeks, or ii) a 10-week waiting period. After the waiting period you will be offered the CBT treatment if you still need it. At the end of the treatment or the waiting period you 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 *completely random*. The reason for asking some children and teenagers 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.

Why are you doing experiments and what will they involve?

We are doing several experiments as part of this study. By doing these experiments before and after the treatment or waiting period we hope to understand much more about what causes PTSD in children and teenagers, and what things help them to get better afterwards.

These experiments are like special tests, where you will have to try to think through or remember certain things. Part of these experiments will involve trying to remember what happened to you during the frightening event, a sad occasion, and a happy occasion. During this procedure we will measure your heart beat to see how you are feeling.

These tests and questions will last for about 2 hours, but you can have breaks during them. As these experiments are not what people normally do if they have help for PTSD, we will pay your parent £30 to share with you for your time and help.

We're 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 you have 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 would also like to take some spit samples on the day you visit us. These samples will allow us to measure a special chemical in your body called a hormone. These chemicals occur naturally and can give us an idea of how you are feeling.

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 Herchel Smith Building, which is next to Addenbrooke's Hospital.

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

We will let your GP (family doctor) know that you are helping with this study.

All information collected about you during the research will be kept strictly confidential – that means we will not tell anything about you to anyone else. Information will only be analysed by scientists at the 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 will *not* be named.

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 saliva (spit) for some genes that we think may affect how young people cope after a frightening experience. We would like to store the part of the saliva that contains your 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 samples after the study. We would need separate permission from an ethics committee to carry out these additional tests after the study. These genes are involved in how our brains work, in particular how we feel. We will not tell anyone else about the results of these genetic tests.

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

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