

VOLUNTEER INFORMATION SHEET: Adolescent with RE

Please read this if you think you might want to take part in our research.

It is completely up to you.

***Study Title: Brain function in children with Rolandic Epilepsy
(Version N^o III: 1st November 2011)***

You are being asked to take part in a research study. Before you decide to take part you need to understand why we are doing this study. Please take time to read this leaflet and talk about it with your family and friends or doctor if you want to. Ask us if there is anything that you do not understand. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

We want to compare the brains of young people with a medical condition called Rolandic Epilepsy with the brains of other young people that do not have this condition. We would like to understand more about how your brain works while you are performing some tasks inside and outside the brain scanner (MRI machine) These tasks measure things like attention, timing, reading and speaking, and are spread over several sessions. Altogether you will do two scans and have two or three extra visits for completing simple tests and questionnaires.

Why have you been chosen?

We are asking 30 young people with Rolandic Epilepsy and who are between the ages of 10 and 14 to take part. We are also asking 30 of their brothers or sisters to take part. We are also asking young people of the same age who have no symptoms of Rolandic Epilepsy to take part.

Do I have to take part?

It is up to you to decide if you want to take part or not. If you do decide to take part you can keep this leaflet and you will need to sign an assent form because you are under 16. Even after you have said yes, you can change your mind at any time without saying why and this will not change the way you are treated by any doctors or anyone else.

What will happen to me if I take part?

We will ask you and your Mum, Dad or carer to come to our clinic, where we will do some simple tests and ask the adult with you to fill in some questionnaires about you. Using a laptop, we will show you the simple computer games which we want you to get used to, and which involve listening for sounds and looking at words, etc. We will ask you to do them all for us – you will probably have to come back on another day to finish them. We will also ask you to come back to the Institute of Psychiatry to do a set of two scans – these will be around two years apart (but it will depend on when your seizures stop). During these scans we will use MRI (magnetic resonance imaging) to see your brain in action. This method does not harm or change anything about you.

On the day of the first scan you will arrive at the hospital where you can practice the computer games again in a normal room. After a little while, we will ask you to do some of them in the MRI scanner. All the scans will last about 1 hour. After the first scan we will ask you to come back for 1 more scan. This scan will be after your seizures have stopped, or around 2 years later.

The information we collect about your brain will be put together with information obtained from other young people, so that we can look at a whole group of brains together.

Is the MRI scanner safe?

The scanner uses a big magnet, which reads signals coming from your brain and with that it can measure activity in your brain. This method is very safe and does not hurt or change anything about you.



This magnet does, however, pull at certain metallic things. You cannot have a scan if you have ever had metal in your eyes, or had metallic objects like clips put into your body in an operation, or if you have ever received a gun injury, or if you have ever had a heart pacemaker. You cannot take anything magnetic into the scanning room and you can leave coins, keys, watches and magnetised cards in the locker provided, or with your mum or dad or carer.

Also, some young people don't like closed spaces. If you don't like closed spaces you may not like to take part in this study.

Each scan is carried out by experienced nurses who are used to operating the scanner. There is a team of nurses to make sure you are okay. There is nothing special you need to do before or after the scan and you can eat and drink as normal. A nurse will go through what a scan involves with you and your mum or dad or carer before you go in. A picture of the scanner is shown above – you might have seen one on TV.

Because we want your pictures to be very good we need you to lie as still as you can in the scanning machine. You will hear loud banging noises but you will wear ear covers to help reduce the sounds. There is a microphone inside the scanner so that you can talk to us if at any time you want the scan to stop.

What is not good about taking part?

The picture of your brain will be looked at by a special doctor who knows how to look at these pictures (a radiologist) to make sure there is nothing abnormal in your brain. If something abnormal is found, we will contact your doctor who will arrange for further investigation. The radiologist will tell us about what they saw in the pictures, too.

What is good about taking part?

The information we get from this study may help us to understand how children develop epilepsy. You will also get some a picture of your brain and feedback about how your brain works.

What if something goes wrong?

If something goes wrong we will make sure you are looked after by following guidelines that we use in the scanning department.

Who will you tell about me?

Anything we find out about you will be kept to ourselves. Any written material or notes about you which leave the scanning department will have your name removed so that nobody will be able to identify you

from your scan. Your GP and any other doctors who look after you will be told that you have taken part in the study. We will ask your Mum or Dad or carer for their names and addresses and will ask you if we can talk to them before you take part.

What will happen to the results of this research?

The results of this study will appear in scientific media but if you are very interested you can have copies sent to you by asking Dr. Anna Smith. However, your name will not be in any of the media.

Who is paying for the research?

This study has been paid for by two health research charities called The Waterloo Foundation and Epilepsy Research UK.

Who has checked the research?

A special group of people have checked that this study is okay for you to do. This group of people is called the London Camberwell – St. Giles Research Ethics Committee and they have a Code number for the study: **10/H0807/93**.

Will I get anything for taking part?

You will receive £30 for each scan. We will also give you £20 each time you and your Mum or Dad or carer complete the simple tests and questionnaires outside the scanner. We will also give your Mum or Dad or carer any bus or train fare back or some petrol money. We will also give you a picture of your brain either by email or on photographic paper. At the end of the research we will send you a bit of information telling you what we have found out.

Where do I write to?

You can write to Dr. Anna Smith at the Centre for Social Genetic and Developmental Psychiatry, PO46, Institute of Psychiatry, De Crespigny Park, London, SE5 8AF for any more information or you can telephone: 0207 848 0755.

We would like to thank you for reading this leaflet.