

VOLUNTEER INFORMATION SHEET: PARENT/CARER

Please read this carefully if you wish to participate in our study

Your participation is entirely voluntary

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

Your child is being invited to take part in a research study. Before your child decides it is important for you and he/she to understand why the research is being done and what it will involve. Please take time to read the following information carefully together and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish your child to take part.

What is the purpose of the study?

During this study, we would like to compare brain activity in young people with Rolandic Epilepsy (RE) and brain activity in other young people that do not have this condition. We would like to understand more about how the brains of these young people work while they are performing some tasks inside and outside the brain scanner. These tasks measure aspects of behaviour which young people with RE often find difficult such as attention, timing, reading and speaking. We would also like to ask your child to undergo another single scan after his/her seizures have stopped or approximately 2 years later (whichever is first).

Why has your child been chosen?

We are inviting 30 young people with a diagnosis of RE who are between the ages of 10 and 14 to take part. We are also asking 30 of their siblings to take part. Finally, we are also asking young people of the same age who have no symptoms of RE to take part.

Does he/she have to take part?

It is up to your child to decide if he/she wants to take part or not. If he/she does decide to take part you will be given this information sheet to keep and will be asked to sign a consent form as he/she is under 16. If your child decides to take part, you are both still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect standard of care he/she receives.

What will happen to him/her if he/she takes part?

We will invite you and your child to come for a meeting at the Institute of Psychiatry, where we will do some simple IQ tests and ask your child and you to fill in some questionnaires, for example about your child's behaviour. Using a laptop, we will train your child on some simple computer games which involve listening for sounds and looking at words, etc. We will then invite your child to return to the Institute of Psychiatry to take part in a set of two scans. Two of these will be approximately two years apart (but it will depend on when your child's seizures stop). We will also ask your child to complete a battery of tasks and questionnaires on two occasions. During the scans we will use MRI (magnetic resonance imaging) to see your child's brain in action. This method does not harm or change anything about your child and no harmful side effects have ever been reported.

On the day of the first scan your child will arrive at the Institute where he/she will have another practice

of the computer games in a normal room. After a little practice, we will ask that he/she do some of them in the MRI scanner. All scans will last about 1 hour.

After the first scan we will ask that you and your child return for another scan after his/her seizures have stopped or approximately 2 years later (whichever is first).

The information we obtain about your child's brain activation at each scan will be grouped together with information obtained from other young people, so that we can compare group performance.

Is the MRI scanner safe?

The scanner uses a big magnet, which reads magnetic signals in your child's brain and which it can convert into a detailed image of his/her brain. It is perfectly safe and has never been shown to be harmful. However, as the scanner is a magnet, it may attract certain metallic objects. Your child must not have a scan if he/she has received metal injuries to the eye, had metallic objects (including clips) inserted into his or her body in an operation, or if he/she has received a shotgun injury, or has a heart pacemaker or a **mouth brace**. Your child will not be allowed to take anything magnetic into the examination room and will be asked to leave such items as coins, keys, watches and magnetised cards in the locker provided, or with you.



Also, some people suffer from fear from enclosed spaces or claustrophobia. If your child dislikes enclosed spaces he/she may not like to take part in this study.

Each MRI scanning session is overseen by experienced radiographers, and the whole team will try to ensure that you and your child have stress-free visits. There is no special preparation prior to the scan and he/she may eat and drink as normal. The radiographer will go through what a scan involves with you and your child before he/she goes into the scanner. Remember, MRI scans do not involve any radiation and are not invasive in any way. No side effects have ever been shown from MRI scanning. There are therefore no after-effects from this examination and he/she may eat and drink as normal afterwards. A picture of the scanner is shown above.

Because we would like the best possible images of your child's brain he/she will be asked to lie as still as possible in the scanning machine (as you would expect with a camera). Your child will hear loud banging noises during the scan but he/she will wear ear protection to protect him/her.

Your child will be in the scanner for about an hour and during that time he/she will be doing the tasks that he/she practised earlier and is familiar with. There is a microphone inside the scanner so that your child can talk to us if at any time he/she wants the scan to stop.

What are the risks and disadvantages of taking part?

In all cases, the brain scan images we acquire will be examined by a clinical neuroradiologist to make sure there is nothing abnormal in your child's brain. In the extremely unlikely event of something unusual being found, we will contact your GP who will arrange further investigation. The neuroradiologist will also inform of us their findings.

What are the advantages about taking part?

The information we get from this study may help us to understand how children with RE develop epilepsy. You will receive some information about 1) your child's intellectual performance 2) about your child's clinical profile (i.e. we can give you the results on the questionnaires we ask you to fill in which will be an indicator of the severity of the RE symptoms of your child) and 3) he/she will receive a picture of his/her brain.

Will there be any compensation for taking part?

Your child will receive £30 for taking part in each scan, and £20 for each completion of the battery of tasks and questionnaires outside the scanner. We will also reimburse any travel expenses and can arrange taxis or other travel for you if required. We can also provide you with an image of your child's brain either by email or on photographic paper.

What if new information becomes available about the medication?

We are not using any medication or treatment in this study. Sometimes during the course of a research project, new information becomes available about the tasks or illness that is being studied. If this happens, we will tell you about it and discuss with you whether you want your child to continue in the study. If you or your child decides to withdraw, his/her care will continue as usual. If you and your child decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw your child from the study. He/she will explain the reasons and your child's care will continue as normal.

What happens when the research study stops?

When the research study stops your child will continue with his/her care as usual.

What if something goes wrong?

If you or your child are harmed by taking part in this research project, we will of course make sure that care is provided for you in the normal way by following our scanning department guidelines, but there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Will my/my child's taking part in this study be kept confidential?

All information which is collected about your child during the course of the research will be kept strictly confidential. Any written material or notes about your child which leaves the scanning department will have his/her name and address removed so that he/she cannot be identified from it or the scan. Your GP and other clinicians treating your child will be notified of his/her participation in the study and we will obtain consent from you for this.

What will happen to the results of the research study?

The results are very likely to be published in scientific media such as the Archives of General Psychiatry and the American Journal of Psychiatry in several years time. If either you or your child is particularly interested in obtaining copies of these reports you should contact Dr. Anna Smith and she will send you copies. At the end of the research we will send you written feedback on the results of this study. Your child will not be identified in any media.

Who is organising and funding the research?

This study has been funded by two health charities, The Waterloo Foundation, and Epilepsy Research UK.

Who has reviewed the study?

This study has been reviewed by the London – Camberwell St. Giles Research Ethics Committee who have ensured that ethical procedures have been followed.

Contact for Further Information

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. Alternatively you can telephone: 0207 848 0755 or email: anna.smith@iop.kcl.ac.uk.

We would like to thank you for reading this information sheet.