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PARTICIPANT INFORMATION SHEET

Thank you for kindly considering taking part in this research study. We are most grateful for your time and for your interest in our research. In this short document we provide further details about our study and other relevant information. Please read this information carefully.

Why is the research being carried out?

Although MRI techniques are already very well developed for taking pictures to help us understand how the brain functions, there is still much to learn about how our brains actually work. By scanning your brain we can find out more about these things. In this 'functional MRI' scan, pictures of your brain will be taken so that we can see how parts of brain begin to 'work' during certain activities. You will be asked to carry out a simple task while lying in the scanner so that we can take your brain pictures. The task involves reading short sentences, looking at images, or pressing buttons, for example. You will be asked to lie on the MRI scanner bed for up to one hour. Usually it takes less time, and we will be scanning only your brain.

What is Magnetic Resonance Imaging (MRI)?

The Magnetic Resonance Imaging (MRI) system, which is commonly referred to as the MRI scanner, uses the combination of a powerful magnet and radio waves to create very high quality pictures of the human body. MRI does not use X-rays. MRI techniques are already very well

developed for taking pictures, commonly referred to as scans, of the human body. However, less is known about, for example, how brain works during certain tasks. . The MRI scanner at the Clinical Research Imaging Centre (CRIC), University of Edinburgh, is dedicated for use in finding out more about these important topics. We have provided a photograph showing the environment of the MR scanner at CRIC below.

Can anyone participate in the study?

If you agree to join the study, we will check that it is perfectly safe for you to be scanned. Although MRI is normally a very safe method of taking pictures, we do not scan people who have a heart pacemaker or who have had surgery involving the insertion of metal clips, or people who have metal fragments in their eyes, perhaps as a result of their occupation. On the other hand, the metals used in operations such as hip replacements are very rarely a reason not to undergo scanning. The Radiographers will check if you are in any doubt. Sometimes we will choose only particular groups to participate in specific studies, for example – only men or only women, only younger or older people or people from different parts of the UK, Europe or the rest of the world.

What if I may be pregnant?

Before we scan you we need to make sure that you are not pregnant. We will ask you about this in our pre-scan check, but please let us know if you think there is a chance that you might be pregnant as this would mean you are not suitable for participation in this study.

What is it like to have an MRI scan?

When you come to the Centre for your scan, you will be asked whether you have read this Information Sheet and if there are any questions which you would like to ask. You will then be asked to sign a consent form.

Radiographers will help you to come into MR scanner area and will guide you to a private changing room for you to change in. We provide secure lockers in which to store your belongings (we have provided some photographs to help you understand this environment below). **You will be asked to place any metal objects, such as jewellery, including body piercings, keys, watches, coins and credit cards, in a locker. Please do not wear any make-up or talc, and you may have to remove contact lenses if you use them. If this is the case, you will be provided with suitable lenses so it would be helpful if you could bring details of your prescription if you have them. Please be aware that you must change out of any clothing that contains metal, such as zips, and bras. You are invited to bring clothes to change into in which you feel comfortable, such as pyjamas or jogging bottoms and top. The scanning room is air conditioned, so it is recommended that you bring a jumper or cardigan and socks.**

When you are ready, you will be asked to lie on the bed and will have your head positioned in the scanner for up to one hour. While you are in the scanner, a series of pictures will be taken of your brain. For part of the scan you will be asked to complete a number of short, straightforward tasks, which involves reading short sentences and pressing buttons with your

fingers. The exact task will be explained to you beforehand. The scanner makes quite loud noises while it operates. For your comfort, you will be provided with ear plugs and headphones. If at any stage during your scan you become worried, or wish to ask a question, you will be able to speak to one of the Radiographers, who will use an intercom to keep in touch with you.

How long does it take?

To help you prepare for your MRI scan, you will arrive at CRIC 30 minutes before you start MR scanning. During this time you will also be given detailed instructions. Then it will take up to 1 hour for MR scanning, including changing your clothes and preparing you to participate in this experimental study. After you finish your MR scan, we will briefly chat about how you felt about the study. Usually a maximum 2 hours of your time will be required for this study.

Compensation

You will receive £20 out of pocket expenses for participation in this study.

What if you happen to find an abnormality incidentally on the MRI scans?

You should be aware that there is a very small possibility of an abnormality being detected in your scan and you are advised to consider whether the finding of an abnormality on your MRI scan might affect, for example, any insurance policies you may hold. The study investigator or CRIC Radiologist will be happy to discuss this further with you, or you may wish to talk to your General Practitioner (GP) before you make your decision.

To help you to put things in perspective, research has shown that, in the case of brain imaging studies, for every 1,000 subjects who volunteer for an MRI investigation an anomaly that potentially requires further investigation may be detected in of the order 50 subjects. In the vast majority of cases these investigations will indicate that no further medical attention is necessary. There may, however, be one or two subjects in whom an anomaly is detected that requires immediate medical attention, and several other cases which the GP should be told about, in case of any future illness. Knowledge of the prevalence of incidental findings in organs other than brain is so far less well established.

So that our research practice meets the highest possible ethical standards, rather than providing ad hoc reporting of incidental findings on research scans we have initiated a procedure at CRIC whereby we take between 5 and 10 minutes to obtain sufficient series of MRI scans complementary to the research scans to enable a medical doctor (i.e. Radiologist) to provide an appropriate report concerning any anomaly that may be detected on the research scans.

To register you appropriately and to allow correct and accurate processing of the information obtained from your scan, we therefore request the name and address of your GP, as well as your Community Health Index (CHI). We will not be able to scan you unless we have these details. If you do not know your CHI number we will be happy to obtain this on your behalf.

Confidentiality

All pictures that are taken within the Centre are entirely confidential, in the same way as all other medical records are. Pictures gathered from the scanner are anonymised, stored and

processed using computers and, after the study is completed, will be copied onto a permanent record which might be studied again at a later time. Information gathered during your scan, once anonymised may also be shared in a public data repository to allow further research to be conducted. In these cases, people cannot be identified from their pictures, and there are strict laws that will safeguard your privacy at every stage.

Voluntary participation

Your participation in this study is completely voluntary. There is no penalty for not participating. There is no penalty either if you choose not to answer any part of our questionnaires but we will not be able to use the scans provided for the study.

Will it be possible for me to withdraw from the study at anytime if I wish?

Of course you do not have to take part in this study, and you may withdraw from it at any time. We are, however, very grateful to you for offering to help us and, if you are willing, you may be asked to come back for extra scans. You will be debriefed following your scan (if desired).

Who to contact if you have questions about the study:

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Professor Laura Cram, Principal Investigator, University of Edinburgh, laura.cram@ed.ac.uk. Tel: 0131 561 5571.

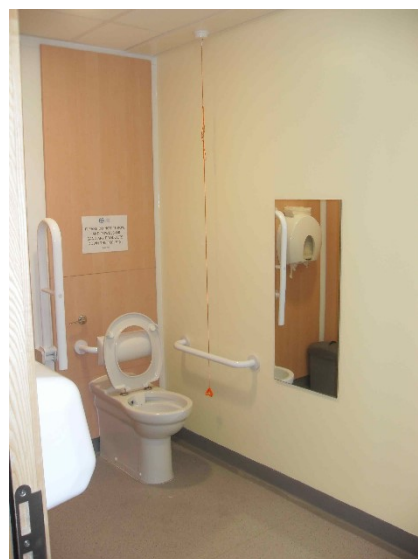
Who to contact about your rights as a research participant in the study:

School Research Director, School of Social and Political Science, University of Edinburgh:
ssps.research@ed.ac.uk

Duncan Martin, Clinical Research Imaging Centre, University of Edinburgh:
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The Clinical Imaging Research Centre and MRI scanner (image courtesy of Siemens Medical Solutions Inc, USA)



CRIC changing room including private cubicle and toilet.