

Study Information Sheet

Healthy Volunteers: 7T

**Study Title:** Standard Functional Magnetic Resonance Imaging (fMRI, at 3 and 7 Tesla) Studies of Cognitive Mechanisms in Normal Adult Volunteers

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read the information sheet carefully and discuss it with others if you wish. Please ask if there is anything you are unclear about or if you would like more information. Take time to decide whether or not you wish to take part: this sheet should be provided to you 24 hours before scanning.

**What is a 7T MRI scanner?**

Since the 1970s, magnetic resonance imaging (MRI) has been shown to be a safe diagnostic imaging procedure. The magnetic field strength of an MRI scanner is measured in Tesla (T). 1.5T scanners are now standard diagnostic tools used within the clinical service, with 3T systems introduced for more specialist clinical imaging. Across the world there are about 60 centres using ultra-high field (7T) scanners for human imaging. Currently such use is for scientific and clinical research only.

**Is a 7T MRI scanner safe?**

Despite the scanner being considered safe, there are some potential hazards associated with MRI and in particular ultra-high field MRI. Therefore, it is essential to follow specific instructions to ensure your safety. The most important instruction is that no magnetic material can enter the MRI room. To ensure this instruction is followed, the operator will ask you some questions about your medical history and talk you through a safety screening check-list. You might be asked to change into MR-safe clothing.

Once ready, you will be escorted into the scanner room, where you may be affected by the static magnetic field. This field, in a 7T environment, can cause temporary dizziness even after exiting the scanner (which typically recovers within 15 minutes). Further, some people may experience slight heating or peripheral nerve stimulation (felt as small muscle twitches). This is not dangerous but may cause slight discomfort. The MRI is certified to stay within the limits considered to be safe. Let the operator know in the event that you feel any such stimulation.

The scanner can be loud when it takes images, so you will be given earplugs and/or headphones to block out some of the sound. Also, the scanner space is quite reduced, and people who are uncomfortable in small or confined spaces may not be able to participate. If this applies to you, remember that you may withdraw from the study at any time without explaining why. Although there is no evidence of danger, as a natural precaution we do not wish to include anyone who may either be pregnant or have any reason to believe they may be pregnant.

MRI is considered a safe method if applied correctly and no indication for any lasting effects on humans has been observed.

**What is the purpose of this study?**

This study will use functional magnetic resonance imaging to measure your brain activity while you engage in standard cognitive tasks. Specifically, we aim to [DESCRIBE MAIN GOAL AND DESIGN OF EXPERIMENT**.** KEEP THE EXPLANATION SIMPLE].

**Who is organizing and funding this study?**

[INSERT NAME] , at the School of Psychology and Neuroscience, Centre for Cognitive Neuroimaging. This research is funded by [INSERT FUNDING INFORMATION].

**Why have I been invited to take part?**

You have been approached by a member of the research team because you volunteered to participate in functional brain imaging studies when you registered on the subject database of the School of Psychology and Neuroscience.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form, and given a copy to take home. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you are a student of the University or any other Glasgow institution, your decision to participate or not will not affect your grades in any way.

**What will happen to me if I take part?**

When you come for your scan, we will discuss the study with you and if you want to take part you will be asked to sign a consent form. A member of the research team will also take you through a pre-scan checklist to make sure that it is safe for you to enter the scanner; this will include some questions about your medical history and the questionnaire will be stored following the study (in an access controlled folder in the NHS radiology Unit, accessible only to NHS approved people, and on an access controlled NHS online system). You will be required to remove all metal/jewellery including piercings prior to entering the MRI room. (Please ensure prior to arrival at your scan session that your piercings can be removed). Once you have been approved to enter the scanner you will be asked to change into MR safe clothing and taken into the MRI room at the Imaging Centre of Excellence, Queen Elizabeth University Hospital, Glasgow.

Once in the MRI room, you will be positioned on the table. Equipment shall be placed over your head that fits like a loose helmet. This equipment is called a ‘coil’ and the information that it receives is what produces the images of your brain. We place cushions around your head that will help to keep your head from small movements, which would affect the quality of the scans. The table will then move into the scanner, and the scan will begin.

You will be given earplugs or headphones to reduce the noise generated by the machine to an acceptable level. It is important that you are able to stay completely still during your scan. Some participants may potentially find the process of an MRI scan claustrophobic. You will be monitored throughout the scan and will be able to communicate with the research team via an intercom should you wish to stop at any time. In most cases, you will see with a mirror mounted on your head-coil towards a projection screen at the back of the scanner bore. We might project images and animations onto the projection screen. In many cases, we will ask you to fixate at the small cross at the centre of the screen and follow further task instructions. The estimated scan time is normally below 2 hours. Durations of scans can be discussed with the scanner operator during each individual scan.

In some cases we may ask you to attend for further scanning if all the required data cannot be collected in one session due to time.

You do not have attend for any repeat scanning if you do not wish and may change your mind at any time, even after a first or second scan, and pull out of the study. Should you wish to withdraw, your data collected up to that point will be retained and used for the remainder of the study, in anonymised form.

**Do I need to do anything before the scan?**

There is no preparation required on your part before having the scan. We will explain the nature of stimulation (e.g. viewing images, listening to sounds), and explain the task to you. It is necessary to come in good health so please report in case you do not feel well or have had bad sleep and feel tired, as this is likely to affect the quality of the scan or your ability to participate attentively. On the day of the scan, please refrain from wearing eye makeup (eyeliner/mascara) or hair products (hair root colour spray/hair fibre spray), as these products can contain small metal particles that might produce artifacts in the image.

**What are the risks involved in participating?**

If you have any implants or devices in or on your body or any tattoos then you may not be allowed to take part in this study. This is because the scanner is a powerful magnet and uses radio-waves, and implants could move or heat up. Similarly, there is a risk that the pigment used in tattoos could heat up during scanning. You will not be allowed to participate if tattoos are located above the armpit. Tattoos located further down on the body are far enough away from the head coil to permit scanning. You will be asked to remove all loose magnetic items (eg coins, hairgrips) before entering the scan room, as they may be pulled towards the MRI scanner. You will be taken through a safety checklist prior to entering the scanner room to determine if it is safe for you to participate. A copy of the checklist is also attached at the end of this document, and we would ask you to read through it and if you have concerns contact [INSERT NAME OF PI] 0141 330 or Frances Crabbe 0141 330 2226. Alternatively please contact Dr John Foster on 0141 452 4218 before your scan if you answer “yes” to any of the questions, or if you have any concerns. It is very important that you answer the safety checklist honestly and that you seek clarification for anything which you do not understand. The safety checklist will be treated confidentially.

**If you have had surgery of any kind or are unsure of any of the answers, it is not a problem, but we will err on the side of caution and will not scan you.**

It is possible that you may feel dizzy when moving around in the scanner room, but especially when you move through the increase of magnetic field strengths at the entrance of the scanner bore. The gradient of magnetic field increase is felt by your inner ear and can give rise to the sensation of moving in a rotation while entering the MRI–bore. This is completely normal, and the feeling will pass when you lie still for a few seconds on the scanner bed or after you leave the scanner room. There are no known long-term effects from exposure to the magnetic field used in 7T MRI.

After your scan, you will be monitored to ensure that any dizziness has passed. Study participants should not drive for 15 minutes after being scanned. A refreshment may be offered while you wait.

There is a very low risk of mercury leakage from amalgam tooth fillings. Please discuss with the researchers in case you are unsure about entering the scanner.

**What are the benefits in my participation?**

You will not receive any direct benefit from the scan, but the information that we get helps further knowledge of the human brain. In addition, your data will be shared. Data sharing is a cornerstone of efficient research; we gain in knowledge by re-using data which in itself can improve health outcomes in patient populations and make better use of the public funds spent on research. We will also compensate you for your travel, time and effort.

**Will I receive a financial compensation?**

To compensate you for your travel and efforts you will receive a financial compensation of up to £15 per hour. [AMEND IF NECESSARY]

**Will my taking part in this study be kept confidential?**

All information that is collected about you, or responses that you provide, during the course of the research will be kept strictly confidential. All images collected from the scans will be anonymised before any analysis is carried out on them, therefore the subject will not be identifiable from the raw data. The MRI anatomy can however be used to create a volume rendering which allows to reconstruct an MRI face which could be used to match your face features. Due to multiple security measures this risk is very low; further details are provided on the consent form.Your personal information will be kept on file and stored in a secure place at the Imaging Centre of Excellence, Queen Elizabeth University Hospital. Your anonymised brain data will be stored at the School of Psychology and Neuroscience, University of Glasgow. Your personal details and data will be kept in University archiving facilities in accordance with relevant data protection policies (GDPR regulations 2018).

As we are working in partnership with the scanner manufacturer (Siemens) to develop 7T imaging protocols your anonymised imaging data might be visible to them on the scanner. However if we choose to share any scans with them for analytical or marketing purposes, such scans will always be anonymised.

In the case of an incidental finding, your data might be de-anonymised but used in compliance will all relevant NHS and University data protection procedures (see section below ‘Will my GP be informed?’)

**How will the images from my scan be used?**

Your images will help us to decide what we need to do to make sure that the scans we use in future research studies are as good as possible. We may also use your images to test analysis software. Your images may be shared with the manufacturer (as above). Your images may be used in scientific presentations and for teaching purposes, but no information will be used that would allow you to be identified. The results of this study will be published in a scientific journal. Most scientific journals require authors to make all data underlying the findings described in their manuscript fully available on an open database. Data sharing is considered best practice in brain imaging research (Nichols et a., 2017. Best practices in data analysis and sharing in neuroimaging using MRI. *Nature neuroscience*, *20*, 299). In accordance with good research practice, they will be kept securely for a minimum of 10 years and possibly indefinitely in the CCNi data archive. All images acquired and stored comply to General Data Protection Regulation (2018) policies. It is unlikely that you can be identified from your anonymised brain imaging data, however there is a small chance. We provide more information in the Open Brain consent form and ask you to acknowledge this possibility before participating.

**Will my GP be informed?**

Before the scan, in the *Consent Form*, you will be asked by the researcher to provide details of your General Practitioner (GP).

***This is not a diagnostic scan***. Because 7T MRI is not in clinical use, your images will **not** be reviewed by a doctor. In the unlikely event that what appears to be an abnormal finding is detected by non-medically trained personnel, we will follow a defined procedure that involves us contacting a health diagnostic professional, either an NHS or non-NHS (outsourced) neuroradiologist for advice. Neuroradiologists might be from an external third party. Should further imaging be recommended in a neuroradiologist report, your name and details will then be added to the MRI image data (de-anonymising) for a follow up referral with the NHS. The researchers may contact you directly to inform you of the recommendation for follow-up clinical investigations, the result of which may be forwarded to your GP and form part of your medical record.

The expert will determine the net benefit of disclosing this information to you. Any information will be given to you by an NHS clinician (consultant neurologist/neuroradiologist), and not by the study researchers.

There are two possible cases:

- Unlikely net benefit: If the incidental finding is a condition not likely to be of serious importance for your health, or whose likely health importance cannot be ascertained, that finding will not be disclosed to you or your GP.

- Potential net benefit: If an incidental finding is discovered which is of potential benefit, it might be followed up under the procedures described above.

However, there is no guarantee that abnormal findings of whatever severity will be diagnosed.

**Are there compensation arrangements if something goes wrong?**

In the unlikely event of anything untoward happening, the University of Glasgow provides insurance for claims.

**What if there is a problem?**

This study is sponsored by the University of Glasgow. The sponsor will be liable for negligent harm caused by the design of the trial, and University of Glasgow Clinical trial insurance applies. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). If you have any complaint about the way you have been dealt with during the study you should discuss this with the research team in the first instance. In the unlikely event that something does go wrong and you are harmed during the research study there are no additional compensation arrangements. The normal National Health Service complaints mechanism is also available to you and the contact telephone number for this is 0141 201 4500.

**Who has reviewed the study?**

The study has been reviewed and approved by the Ethics committee of the [College of Medical, Veterinary & Life Sciences](https://www.gla.ac.uk/colleges/mvls/), University of Glasgow, and is supported by the NHS Greater Glasgow & Clyde Research and Innovation Department. The MRI research environment is overseen by Tracey Hopkins, Lead Research Radiographer, NHS; and Dr John Foster, Head of MR Physics group, NHS.

Thank you for taking the time to read this information sheet. If you have any questions or would like some more information, please feel free to contact a member of the research team and discuss it with them.

Thank you for reading this study information sheet.

The project will end [PROVIDE APPROXIMATE END DATE]. If you are interested to hear more, please contact one of the persons listed below.

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