Participant Information Form

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Name of Principal Investigator:

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Title of Research:
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**We would like to invite you to take part in our research study.**

* Below you will find some information about our study. Please take time to read the information carefully. It is important for you to understand why this research is being done and what it would involve for you.
* Please ask us if there is anything that is not clear or if you would like more information.

***What is the study about?***

[objectives].

**What will be expected of me as a participant?**

[procedure]. The whole experiment will last approximately [duration] .

**Will it be confidential?**

The personal information that you provide during the study will be stored and processed in strict accordance to the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018. Any screening or identifying data collected by us, the researchers, will be stored separately from the experimental data (MRI images), on encrypted devices and destroyed upon publication of the results. Your personal identifying data (e.g., name, email address) will only be accessible by the researchers directly involved in the study.

**Will it be anonymous?**

Your experimental data will be fully anonymized using a unique code and it will not be possible to link the data back to your identity. The anonymizing code will be generated from information that only you know, in such a way that it will be possible for you to retrieve your data if you wish to withdraw from the study (see below); however it will be impossible to identify you from the experimental data we collect.

**How will my data be used?**

The data from the study will be analysed by the research team. Over the coming years, results may be presented at scientific meetings, published in scientific journals, or published on our website. It will not be possible for anyone to identify you from the results, as only aggregated results will be reported.

Sometimes, new methods to analyse data become available after a study has ended. Therefore, we ask for your permission to share your anonymized study data as “open data”. This means the anonymized study data will be publicly available to other researchers both inside and outside the European Union. Your anonymised scan data may be used in future studies for purposes not related to this study. It will not be possible to identify you from these data.

With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

**What are the benefits of taking part in this study?**There is no direct benefit to you. We hope that we will gain useful information about [...]. , which may help inform future studies.

You will receive [£?]. in compensation for your time.

**What are the risks of taking part in this study?**MRI is safe and non-invasive and does not involve any ionizing radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. We will ask you to complete a safety questionnaire to make sure that you do not have any metal in your body. Normally, MRI scanning for research purposes is not performed without further investigation if you have a heart pacemaker, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence to suggest that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. We do not test for pregnancy as routine, so if you think you may be pregnant you should refrain from taking part in this study.

As the scanner can be noisy, we will give you earplugs. It is important that these are fitted correctly as they are designed to protect your hearing. Some people may experience a mild dizzy sensation as they are moved into the MRI scanner. This is normal and the sensation will fade as soon as you are in the scanner. You will be introduced carefully to the scanner and will be allowed to leave at any stage. While you are in the MRI scanner, you can tell us to stop the scans using the handheld buzzer to speak with us if you feel discomfort or do not wish to continue with the scan. Some people who do not like small spaces (“claustrophobia”) might dislike having an MRI scan. If you think you might be claustrophobic, please discuss this in advance with us.

It is important to note that ***we do not carry out scans for diagnostic purposes*,** only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor’s appointment. Occasionally, however, we may see something in a scan that we think is worthy of further investigation by a qualified professional. In this case, we will contact your GP. No information other than your name will be conveyed unless you specifically request it. You would not be informed unless the doctor considers the finding has clear implications for your current or future health.

**Can I withdraw from the study?**

You may at any time discontinue the study without penalty. You may also withdraw up to 1 month after you have completed the experiment, in which case we will destroy your data.

**How will I notify my intention to withdraw?**

If you wish to withdraw, you simply need to notify the experimenter during the session. If you would like your data to be destroyed, contact the lead researcher (see below). You will be asked to provide the information needed to regenerate your anonymizing code and retrieve your data.

**Who should I contact with queries, concerns, or complaints?**

Contact the lead researcher, [name, email]. in the first instance of a query, concern or complaint. If you have any concerns or complaints about the Ethical conduct of this study, please contact the Research Administrator, Faculty of Health Research Ethics and Integrity Committee, University of Plymouth, Level 2 Marine Building, Drake Circus, Plymouth PL4 8AA Email: FOHEthics@plymouth.ac.uk

**Thank you for reading this information sheet.**