LETTER OF INFORMATION FOR NEUROIMAGING PARTICIPANTS

The neural mechanisms of rhythm and music perception

Principal Investigator:

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Introduction

You are being invited to participate in a research study investigating the regions of the brain that are active when people perceive music or the sequences of events that form a rhythm. You are being asked to participate as a normal, healthy volunteer. The purpose of this research is to map and characterize areas of the human brain which are involved in our natural sense of music, musical rhythm, and “feeling the beat”. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to understand why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is unclear or there are words or phrases you do not understand.

Research Procedures

If you agree to participate in this study, you will undergo functional magnetic resonance imaging (fMRI) at the Robarts Research Institute. Functional MRI is a noninvasive brain imaging technique that uses the same machine that is used in MRI for patients. MRI uses a strong magnet and radio waves to make images of the brain. It does not involve x-rays or radiation. When a specific region of the brain is involved in processing information, there is an associated change in brain metabolism and blood flow to that region. These changes can be detected by the MRI scanner as changes in the image signal intensity. These changes are particularly prominent with stronger magnetic fields, which is why we use 3 and 7 Tesla scanners.

Eligible participants will also be asked to remove any metallic personal effects (jewellery, watch, hair clips, wallet) to be stored in a safe place while being scanned. At the beginning of the session, you will lie down on a table that slowly slides inside the long hollow tube at the centre of the MRI machine. The space within the large magnet is somewhat confined, although we have taken many steps to reduce any "claustrophobic" feelings. The session will last up to two hours, during which you must keep as still as possible, especially during periods lasting approximately five minutes during which the magnet is beeping continuously. You will be made comfortable with pillows, blankets, and foam to help keep your head still. You will hear a muffled banging and beeping noises throughout the scanner operation, but the hearing protection will reduce the sound level to an acceptable level. You will be in voice contact with the operator while you are in the scanner. Between scans we will remind you of specific instructions of the next task. If you want to alert the operator during a scan (i.e., if

you find the sound uncomfortably loud), you can use the squeeze ball to end the scan session. Of course, you may ask the operator to end the experiment at any time.

During the functional scans, you will hear sounds and may be asked to listen passively, or make perceptual judgements about the sounds, and/or make responses to the sounds. If the task is complex, you will be given a chance to practice before the scan session.

If you are part of a study that involves a follow-up session, you will also be invited for behavioural sessions in between the scan sessions, and will be invited back for a follow-up neuroimaging session. Behavioural tasks may involve passive listening, discrimination, and reproduction tasks. For discrimination tasks, you will listen to the stimulus, then have to make a judgement about a characteristic of that stimulus (e.g., 'does it have a beat? Is it the same rhythm as the previous stimulus?). Reproduction tasks involve reproducing some aspect of the stimulus, for example to tap the rhythm after perceiving it.

Voluntary Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer questions or withdraw from the study at any time with no effect on your academic or employment status. You should ask to stop the experiment if you feel uncomfortable, claustrophobic or tired. If you happen to be invited back for behavioural testing or a second scan, continued participation in these aspects is also entirely voluntary.

Compensation

Neuroimaging: You will be compensated $25/hr to cover your time, parking and the inconveniences associated with participating in the neuroimaging components of the study. This will be paid after each scanning session.

Behavioural testing: You will be compensated $10/1.5 hours for your participation in behavioural testing outside of the scanner. Passive music listening components that take place at home will not be compensated.

Benefits

While this study will not result in any direct benefit to you, it may help clinicians understand how the brain responds to rhythmic information and therefore be of some benefit to patients in the future.

Risks

The Food & Drug Administration (USA) has indicated that for clinical diagnosis an 'insignificant' risk is associated with human MRI exposure at the intensities used in this project. Current Canadian guidelines follow the USA guidelines. Although very rare, injury and deaths have occurred in MRI units from unsecured metal objects being drawn at high speeds into the magnet or from internal body metal fragments of which the subject was unaware or had not informed MRI staff. To minimize this latter possibility it is essential that you complete a screening questionnaire. Other remote but potential risks involve tissue burns and temporary hearing loss from the loud noise inside the magnet. The latter can be avoided with ear protection that we will provide for you. This ear protection also allows continuous communication between you and the staff during the study.

Participant Exclusion Criteria

The most important safety concern with MRI is to avoid having any metal in your body that is deemed unsafe in a strong magnetic field. Prior to participating, you will be asked to fill out a screening checklist to evaluate whether you meet the eligibility criteria for participation in this fMRI study. These include precautions to ensure you have no unsafe metal in your body and, if you are female, that you are not pregnant or at risk of conceiving a child. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop or been a soldier, if you have some type of implanted electrical device (such as a cardiac pacemaker), if you have severe heart disease (including susceptibility to arrhythmias), you should not have an MRI scan. Some surgical implants (e.g., hip or joint replacements) are made of alloys (e.g., titanium) that are non-magnetic and are therefore safe in the MRI scanner. To certify that your surgical implant is safe for the MRI, we must have documentation from your physician before you will be able to participate in the experiment.

Confidentiality

Any information obtained from this study will be kept confidential. In the event of publication, any data resulting from your participation will be identified only by case number, without any reference to your name or personal information. The data will be stored on a secure computer in a locked room. Both the computer and the room will be accessible only to the experimenters. After completion of the experiment, data will be archived on storage disks and stored in a locked room for five years, after which they will be destroyed. Representatives of the University of Western Ontario Health Sciences Research Ethics Board may require access to your study-related records or may follow up with you to monitor the conduct of the study.

Estimate of participant's time and number of participants

Each experimental session will not last longer than approximately two hours. The entire research project will involve approximately 800 subjects.

Consent Form

You do not waive any legal rights by signing the consent form. You will be provided with a copy of this letter of information and the consent form.

Contact Information

If you would like to receive a copy of the overall results of the study, or if you have any questions about the study please feel free to contact the Principal Investigator at the contact information provided above.

If you have any questions about your rights as a research participant or the conduct of the study you may contact:

The Office of Research Ethics
The University of Western Ontario
519-661-3036
E-mail: ethics@uwo.ca

CONSENT FOR RESEARCH STUDY

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I have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

_____	_____
Name of Participant (Please print)	Date
_____	
Signature of Participant	
_____	_____
Name of Experimenter (Please print)	Date
_____	
Signature of Experimenter	