

Description

Brain imaging data will be collected in the 7T MRI scanner. Physiological measurements will be collected using a BIOPAC MP150WSW data acquisition system, an ECG MRI-compatible amplifier (BIOPAC product ECG100C-MRI), an EDA MRI-compatible amplifier (BIOPAC product EDA100C-MRI; for more on all MRI-compatible amplifiers, please refer to <https://www.BIOPAC.com/product-category/research/mri-magnetic-resonance-imaging/amplifier-modules/>), and a respiration amplifier (BIOPAC product number RSP100C) with all cables to and from the amplifier being MRI-compatible (BIOPAC product numbers MECMRI-BIOP and MECMRI-TRANS). All corresponding radiotranslucent leads (BIOPAC product LEAD108) and electrodes (BIOPAC products EL508/EL509) are MRI-compatible as well. Physiological data acquisition will strictly adhere to safety standards set by BIOPAC (for more on MRI safety awareness with regard to physiological data collection, please refer to <https://www.BIOPAC.com/wp-content/uploads/MRI-Recommended-Reading.pdf>). Electrodes will be applied according to standards set forth for safety, and in accordance with previous literature (for ECG, please refer to <https://www.intechopen.com/books/advances-in-electrocardiograms-methods-and-analysis/electrocardiogram-in-an-mri-environment-clinical-needs-practical-considerations-safety-implications->; for skin conductance, please refer to http://www.BIOPAC.com/Manuals/mri_7_rmc_appendix.pdf). Physiological data collection is performed by a high-end HP 6570b notebook PC with Windows 7 Professional, AcqKnowledge BIOPAC software, mobile Intel HM76 chipset, 8GB 1600MHz DDR3 SDRAM, and a 500GB 7200rpm SATA hard drive. AcqKnowledge is an interactive and intuitive data acquisition and analysis software program for the collection of psychophysiological data. It interfaces with a variety of modules for triggering, allowing for time-synced acquisition. Data between the amplifiers and the PC is transmitted via an Ethernet high-speed cable for recordings up to 400KHz.

Potential Risks and Discomforts

Projectiles
Torsion and translational forces
Magnetohydrodynamic effects
Peripheral nerves stimulation
Acoustic noise
Induced currents and electrical interference
Radiofrequency heating
Suffocation (very rare).
Burns from tattoos or permanent makeup
Claustrophobia
Nausea
Emotional discomfort

Consent Form Language

Physiological Measurements (Description)

We will be recording some physiological measurements while you are in the scanner. Specifically, we will be recording skin conductance (if the hands get sweaty), respiration (how you are breathing), and heart rate measurements. These measures will allow us to better understand how your body reacts to cognitive and emotional tasks. To collect this data, we will need to put 5 MRI-compatible electrodes on your body. The experimenter can put on these electrodes, or you can put them on. A diagram will be provided to you if you would like to put them on. There will be two electrodes placed on the middle and ring finger of your non-dominant hand. We will also place three electrodes on your chest – one near your right collarbone, one just below your left collarbone, and one close to your sternum. Finally, we will place a belt

around your chest to measure your breathing. If you feel uncomfortable at any time, you may discontinue the experiment, or choose not to wear the electrodes.

Risks and Discomforts

The risks associated with participating in this study are:

1. The most obvious personal risk from having an MRI is blunt trauma due to metallic objects being brought into the magnetic field. As such, all necessary steps will be taken to make sure neither you nor anyone else who enters the MRI scanner room is in possession of an unrestrained metal object and no unauthorized person will be allowed to enter the MRI scanner room.
2. Participants who have steel or iron implants or clips from surgery within their body or metallic objects such as shrapnel or metal slivers in their body, should not participate in this study as the magnetic field may pull these objects resulting in injury.
3. The MRI machine produces an intermittent loud noise that some people find annoying.
4. Some participants may feel uncomfortable being in an enclosed place (claustrophobia) and others find it difficult to remain still. This may be more noticeable in 7T MRI scans due to the smaller bore size.
5. Some people may experience dizziness or a metallic taste in their mouth if they move their head rapidly in the magnet.
6. Some people experience a brief period of nausea when being put into or taken out of the scanner. This is more prominent in 7T MRI scans due to the increased magnetic field and the effects of the shielding.
7. One of the potential risks to be considered in this study includes the risk of revealing personal and sensitive information on the part of the participant. Participants will be asked personal questions regarding their health status.
8. Another potential risk is discomfort to the participant associated with being asked to reveal personal information.
9. Some people may feel uncomfortable putting electrodes on, or taking electrodes off, of their skin. You may choose not to participate.
10. In rare cases, electrodes or the electrode leads/wires may heat up and cause burns.

Although long-term risk of exposure to the magnet is not known, the possibility of any long-term risk is extremely low based on the information accumulated over the past 30 years.

Minimizing Risks and Discomforts

To minimize the risks and discomforts associated with this study, we will:

1. Screen for whether you have iron or steel implants, clips from surgery, or other metallic objects in your body over the phone (before scheduling a visit) and have you fill out screening forms at the fMRI visit. If you have implants, clips, or objects in their body, you may not be able to undergo an MRI scan. We will also ask about this over the phone when scheduling you.
2. Ask you to change into surgical scrubs supplied by the center and remove any watches, rings, earrings, or other jewelry and metallic objects. You will be provided a private place to change and you may retain your undergarments.
3. Scan you with a handheld metal detector to detect any unknown metallic objects.
4. Provide you with a set of ear plugs designed to protect your ears in an MRI scanner.
5. Maintain visual and verbal contact with you during the scan and check with you frequently to determine if you are having any negative feelings or sensations. No more than 8 minutes will pass between verbal contact (on average, this is closer to 5 minutes).
6. Provide you with a pillow under your knees to minimize discomfort from lying down for a long period of time.

7. If some unknown risk becomes a safety issue, the research team will immediately stop the scan and remove you from the scanner.
8. You can stop the scan at any time and be immediately removed from the scanner. This is accomplished with a squeeze ball that you can squeeze at any time during the scan.
9. To protect the confidentiality of all information, consent forms attained will be immediately collected and placed in a locked cabinet. While the probability of a breach of confidentiality is low, the magnitude of social harm if a breach of confidentiality occurs is high especially with respect to the sensitive items (i.e., medical history). All forms will be coded with your study-specific, unique participant identification number, and stored in a private office, in a locked filing cabinet. Electronic data will be on password-protected computers and servers with limited access to only the investigators on this study.
10. All data will be stripped of identifiable information and provided with a study specific unique participant identification number.
11. To minimize the risk of discomfort by revealing personal information, you will be given the option to refuse to answer most questions without penalty or exclusion from the study, except for those presented in the screening process, which are necessary to ensure you safety and eligibility.
12. To prevent the leads coming from your electrodes from overheating, we will ensure that all wires do not form loops. We will also place a barrier between the wires and your skin (i.e., clothing, a towel, or something similar).