High-resolution fMRI study of functional architectures as well as sensory and cognitive functions in the human brain (Normal Operation Mode)

Explanation

1. Introduction

The objective of this experiment is to use high-resolution fMRI to reveal functional architectures and to explore neural mechanisms underlying various sensory and cognitive functions in the human brain.

This experiment has been approved by the Research Ethics Committee of RIKEN. The essence of the experiment is explained below. Please decide if you are willing to participate in the experiment after you read through and fully understand the description. Even if you decide not to participate in the experiment (or decide to quit in the middle of the experiment), your decision will not lead to any unfavorable consequences. Please read and confirm the explanation below carefully. If any part is difficult to understand or if you have any questions, please do not hesitate to ask the experimenter for further clarification.

2. Conditions for participation

Subjects participating in this study should be healthy adults, at least 20 years old. Those who have past/current experiences of 1) epileptic seizure, 2) using pacemaker or other artificial organs, 3) retaining metal fragments in the body, whose non-magnetism cannot be confirmed, 4) having difficulty with body-temperature regulation, 5) communication disorder (trouble speaking or hearing), 6) having or having had an occupation or haven taken part in previous activities that may result in accidental retention of magnetic objects in the body, or 7) claustrophobia and other phobias, as well as females who are currently pregnant, cannot participate in the experiment.

3. Contents of the experiment

This experiment will be conducted with an MRI system whose magnetic field strength is either 3 or 4 Tesla. The objective of this experiment is to use high-resolution fMRI to reveal functional architectures and to explore neural mechanisms underlying various sensory and cognitive functions in the human brain. Only one experimental session is scheduled per day for each subject, and each session is concluded within 2 hours. During these 2 hours, you will enter and remain inside the magnet bore, and will be asked to press the response buttons to report the results of certain cognitive processes in response to visual, auditory or other types of stimuli. The anatomical structures or neural activity of your brain will be measured using the MRI system. The measurement will be repeated several times. While inside the magnet bore, in between measurements, please rest while maintaining the same posture as that during the measurement. In addition, in order to compare the brain under different experimental conditions, you may be requested to participate in measurements over multiple days. In that case, your agreement to participate will be obtained separately each experimental day.

4. The safety of the experiment

The measurement procedure in this experiment is more or less the same as the checkup commonly performed in hospital. There have been no reports of harmful influences caused by measurements using MRI systems at these field strengths. However the possibility that the exposure to magnetic fields of these strengths may have harmful influences cannot be completely ruled out at this time.

During the measurement, at least two experimenters will be at the site, constantly monitoring your health state. In addition, your agreement will also be obtained on another set of explanations and informed consent, prepared by the Support Unit for Functional MRI.

5.Period of this research theme and collaborators

This research proposal expects to be finished at March 31, 2019. However, it may be extended longer depending on the progress of the research.

We have had collaborations with Tokyo University, Tohoku University, Saitama University, National Taiwan University and Kao Corp. for this research project. We may have additional collaborators in the future.

6.Agreement on participating the experiment

This experiment will be conducted based on your agreement to participate in the experiment. If you are not willing to participate in the experiment, you will not bear any unfavorable consequences. Furthermore, even after you agree to participate, the experiment can still be terminated before it is started or during the measurement. You will not bear any unfavorable consequences under these circumstances, and your personal information as well as any measurement data collected from you by then will be discarded.

Any time after the experiment, we will discard the experimental data obtained from you upon your request to the operator or the Wako Safety Center, RIKEN. However, we cannot do so after we publish the results.

7. Privacy protection

Your privacy related to this experiment is strictly protected. Your name and any information that may lead to personal identification will not be reported in professional conferences or published in papers. Your personal information and the experimental data collected from you will be stored in secured places and managed safely (with linkable anonymization). Therefore, you do not need to worry that this information might be leaked to the third party.

8. Disclosure of the result

We ask for your understanding that we cannot respond to your inquiries regarding the measurement results. However, if you wish, the measurement results can be shown to you immediately after measurements are finished, before they are analyzed. We cannot show the results after the data are processed and analyzed.

9. Regarding the results from this experiment

In the case that the results from this experiment lead to the rights of any intellectual property such as the right of a patent, these rights belong to RIKEN.

10. Practicing structure of this experiment

This experiment is primarily conducted by our research team, the Team for Cognitive Brain Mapping, however we may share the acquired data with collaborators outside of RIKEN, including foreign countries.

This research is carried out using RIKEN 's research budget, research grants or funding from the private company, Kao Corp. It has been confirmed that there are no Conflicts Of Interest (COI) with any outside companies by RIKEN’s COI committee.

11. Complaints about the experiment

To complain, please contact the Wako Safety center of RIKEN (direct phone: 048-467-9293).

Experimenter: _____

Responsible Investigator: Keiji Tanaka (Laboratory Head)
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Informed Consent

Keiji Tanaka, Laboratory Head
Laboratory for Cognitive Brain Mapping
RIKEN Brain Science Institute

1. Before I participate in the experiment titled "High-resolution fMRI study of functional architectures as well as sensory and cognitive functions in the human brain" (hereafter referred to as the experiment) as a subject, I have received an explanation from the experimenter regarding the objective and nature of research of the experiment, which I fully understand and agree with. I therefore decide, of my own free will, to participate in the experiment.

2. I understand that before the start of the experiment or in the middle of the experiment, I, of my own free will, can cancel or decline to participate in the experiment for whatever reason at any time.

3. I have agreed to participate in the experiment based on the following explanation that I received from the experimenter:
   1) In case any accident or problem takes place during the experiment, the experimenter will take emergent measures to ensure the safety of the subject.
   2) Participation in the experiment or quitting in the middle of the experiment will not result in any unfavorable consequences to the subject.
   3) If the subject has complaints regarding the experiment, the subject can directly consult the Research Ethics Section, Safety Division of RIKEN (direct phone: 048-467-9293).

4. I am a healthy adult (20 years old or above) and have no past/current experiences of 1) epileptic seizure, 2) using pacemaker or other artificial organs, 3) retaining metal fragments in the body, whose non-magnetism cannot be confirmed, 4) having difficulty with body-temperature regulation, 5) communication disorder (difficulty speaking or hearing), 6) having had an occupation or taking part in previous activities that may result in accidental retention of magnetic objects within the body (i.e. welding, grinding metal, etc.), or 7) claustrophobia and other phobias.

5. I am not currently pregnant (this clause applies to females only).

6. I understand that in case experimental results lead to the rights of any intellectual property, such as the right of a patent, these rights belong to RIKEN.

Experiment date (D____M____Y_____) Explanation date (D_____M_____Y_____)

☐ Male ☐ Female Age _____ Person who explains _____

Signature _____

Subject ID number:

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