CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: "Effect of Mental Imagery Training on Brain Plasticity and Motor Function in Individuals with Parkinson's Disease: A functional MRI investigation"
Principal Investigator: Dr. Sule Tinaz
Funding Source: Department of Neurology, Yale School of Medicine

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the effect of mental imagery training on brain function and motor performance in Parkinson's disease using magnetic resonance imaging (MRI). You have been asked to participate because you have been diagnosed with Parkinson's disease. In total, this study will aim to enroll seventy individuals with Parkinson's disease.

Mental imagery means forming mental pictures in the mind. Various forms of mental imagery have been used in psychology for health or performance benefits. This study will use a combination of two types of imagery: 1) Visual imagery of, for example, shapes, colors, or spaces and 2) Motor imagery which refers to the mental rehearsal of movements without overt movement. You will practice mental imagery of everyday task performance (e.g., preparing a meal, grocery shopping) in the MRI scanner. You will also watch video footage of everyday task performance in the MRI scanner. MRI is a medical imaging technique that uses magnetic fields to take pictures of structures inside the body. In this case, it will show us how your brain behaves during mental imagery and video watching.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, you will be asked to complete one research visit including clinical evaluations and MRI scanning sessions with a total time commitment of approximately 3 hours. The clinical evaluation will include a neurologic and cognitive examination to determine eligibility, as well as self-evaluation questionnaires. All visits will take place in the morning. You will continue to take your dopaminergic medications as scheduled. The details of the procedures are described below.

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Screening

If you are a woman younger than 50 years of age and have your menses, you will receive a urine pregnancy test.

Clinical Evaluation

A standard neurological and physical exam will be performed by one of the neurologists working on this study. Your motor function will be evaluated using the standard Parkinson's disease rating scale. During this evaluation, you will be asked to perform simple tasks, such as tapping your fingers, holding your arms stretched out in front of you, or stomping your foot on the ground. Then, a brief test will be used to test your cognitive function in areas such as memory, attention, and language. Additionally, you will be asked to fill out brief questionnaires with questions about your emotions, fatigue level, quality of life, and imagery skills. If you fulfill the clinical criteria, you will be enrolled.

You will then practice mental imagery of everyday task performance under the guidance of a research team member. You will also watch sample video footage of similar everyday tasks.

MRI experiments:

The MRI session will include both structural imaging, which shows us what your brain looks like, and functional imaging, which shows us how your brain behaves in certain situations. During this time, you will simply have to lie down in the scanner while staying as still as possible for the duration of each individual scan. First, a structural scan of your brain will be collected (5 minutes). Then, the imagery sessions will start during which you will be asked to perform mental imagery of everyday tasks that you practiced before scanning to increase your brain activity. There will be 4 mental imagery sessions each lasting 4 minutes. After each mental imagery session, you will be asked basic questions which you will answer by pressing a button. After the mental imagery sessions, the video-watching sessions will start. You will watch video footage of everyday tasks in the scanner. There will be 4 video-watching sessions each lasting 4 minutes. After each video-watching session, you will be asked basic questions which you will answer by pressing a button. The total duration of the entire MRI session will be not more than 1 hour. Upon completion of the MRI experiments, there will be a short debriefing session to assess your memory of the mental imagery and video-watching tasks.

Risks and Inconveniences

Magnetic Resonance Imaging

MRI is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

You will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time and we will take you out of the MR scanner. On rare occasions, some people might feel dizzy, get an

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upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them.
There are some risks with an MR study for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MR scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet. The scanner makes a thumping noise which can be loud enough to damage hearing. Therefore, you will be fitted with ear plugs to protect your ears.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be made available for health care purposes.

Other

The neurological and cognitive testing components of this study are not associated with any physical risks. However, some questions may make you uncomfortable, and there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Note: During the clinical evaluation, if your answers to the questionnaire to assess your emotional wellbeing indicate feeling quite down and blue, we will provide you with information about mental health counseling services and referrals. If your answers to this questionnaire indicate imminent risk of self-harm, we will refer you to the Yale New Haven Hospital Emergency Department on the same day for further evaluation.

Benefits

You might benefit directly from your participation in this research study. We hope that the knowledge gained from this study will lead to improvements in the diagnosis and treatment of Parkinson's disease in the future.

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Economic Considerations

You will be reimbursed for your time and receive $50 for a completed session using a prepaid Bank of America card. Reimbursement for parking will also be provided. Participants' name, address, and telephone number will be shared with Bank of America. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.

Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of elderly abuse and neglect, or harm to self or others.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator (PI) will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. Electronic records will be kept on password-protected research computers. The imaging data will be stored on secure and HIPAA compliant servers in the MRRC. We will use desktop computers and all team members' computers are password protected, in locked areas, and encrypted.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Upon completion of the study, study binders will be stored in a locked facility for the amount of time required by law. After this time, the study binders will be destroyed by shredding. The database that contains our case report form pages will stay on our computer until

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the study closes and the PI signs off on the pages. The link to your personal information will be kept until the end of the study, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

The information about your health that will be collected in this study includes: Medical and laboratory records of only those services provided in connection with this study and research study records including physical exams, questionnaires, paper-pencil tests, and behavioral data. Information about you and your health which might identify you may be used by or given to: Representatives from the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) who may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential; those individuals at Yale who are responsible for the financial oversight of research including billings and payments; study coordinator and members of the research team; Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor Sule Tinaz as soon as you are able. Dr. Tinaz will provide assistance to you in accessing medical treatment through referral, or you may choose to access treatment on your own.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, all necessary treatment will be provided by the treating physician according to standard of care. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care,

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and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital. When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Sule Tinaz, MD, PhD at the Yale University, Department of Neurology, 15 York Street, PO Box 208018, New Haven, CT 06520-8018.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Reasons for Termination from the Study

Your participation in the study will be terminated under the following conditions: 1) If you develop a serious medical condition. 2) If you are not compliant with protocol evaluations. When your participation is terminated, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

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Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Relationship:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Sule Tinaz, at 203-737-6158.

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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