

Initial Stages of Visual Perception Consent Form

PRINCIPAL INVESTIGATOR: Dr. Thomas Spalek, Professor, Department of Psychology, Laboratory of Attention, Memory & Perception, Simon Fraser University, tspalek@sfu.ca, (778) 782-3105.

COLLABORATORS: Dr. Vincent Di Lollo, Adjunct Professor, Department of Psychology, Laboratory of Attention, Memory & Perception, Simon Fraser University, enzo@sfu.ca, (778) 782-7055.

Nadja Jankovic (Ph.D. Candidate), Laboratory of Attention, Memory & Perception, Simon Fraser University, njankovi@sfu.ca, (604) 868-9085.

You are being invited to take part in this research study because you have answered our advertisement and are between the ages of 18 and 35 years, with normal or corrected to normal vision, and without any pre-existing neurological conditions or history of traumatic brain injury. The results of this study will provide valuable information on how the human brain perceives and recognizes objects.

When we say "you" or "your" in this consent form, we mean the research participant; "we" means the principal investigator, co-investigator(s), and other research staff.

Participation is Voluntary: You do not have to participate in this research study. It is important that before you make a decision to participate, you read the rest of this form. Please read the following form carefully and ask questions if anything is not clear. This consent form will tell you about the study, why the research is being done, what will happen during the study and the possible risks, benefits, and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide that you would like to participate, you are still free to withdraw from the study at any time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reason for the decision, and you will not be penalized in any way.

Please take time to read the following information carefully.

BACKGROUND

While we have learned a lot about the brain so far, very little is known about some basic cognitive functions. For example, the process of recognizing your car probably seems automatic. However, there are many complex brain processes involved in perception which we do not fully understand yet. From the moment that light enters your eyes to the moment you recognize an object, your brain processes different aspects of the visual information at different points in time. In the past, it was thought that different brain areas worked separately to process only one aspect of visual information, such as contours or colour. However, evidence suggests that the same brain area may take part in processing different aspects of the image at multiple points in time.

PURPOSE

The main goal of this research is to learn how your brain's visual areas communicate during the different processing stages of object perception. By using targeted magnetic pulses to disrupt the processes at different points in time, we will gather valuable information about the timing and order of these processes and about the brain networks involved in object perception.

WHO CAN PARTICIPATE IN THIS STUDY?

You may be eligible to participate in this study if you meet the following criteria:

- You are between the ages of 18 and 35
- You have normal vision, or your vision is corrected-to-normal using contact lenses

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

If any of the following conditions apply to you, you are at an increased risk while undergoing transcranial magnetic stimulation (TMS). You should not participate in this study if:

- You have had at least one seizure in the past, or you have a family history of epilepsy
- You have a history of a neurological condition, traumatic brain injury, or certain psychiatric condition such as bipolar disorder or substance use disorder
- You have a substance dependence, including excessive alcohol or drug use. A substance dependence
 may put you at a higher risk for having a seizure while undergoing TMS
- You require eyeglasses and do not use contact lenses
- You are pregnant, or think you may be pregnant
- You suffer from a chronic sleep disorder
- You have a history of fainting spells
- You suffer from tinnitus (i.e., ringing in the ears)
- You have been diagnosed with Autism
- You have a movement disorder or tremor
- You are currently taking, or have taken in the last 6 weeks, medications in the following categories:
 - Antidepressants
 - Anticonvulsants
 - Anxiolytics
 - Antipsychotics
 - Stimulants
 - Antiretrovirals
 - Antivirals
 - Antibiotics

- Antihistamines
- Opiates
- Chemotherapy medications

If any of the following conditions apply to you, you may not be eligible to participate in the magnetic resonance imaging (MRI) portion of the study. However, you may still be eligible to participate in other aspects of this research, such as the TMS session.

- You are uncomfortable in small, tight, enclosed spaces (i.e., you have claustrophobia)
- You have had surgery or a tattoo within the past 6 weeks
- You have any implants in your body, such as:
 - pacemaker
 - copper intrauterine device (IUD)
 - o brain aneurysm clip
 - cochlear implant
 - electrical stimulator for nerves or bones
 - o implanted infusion pump
 - history of any eye injury involving metal fragments
 - o you have been a metal worker (grinding, machining, or welding)
 - o artificial heart valve
 - o orthopedic hardware (artificial joint, plate, screws, rods)
 - o other metallic prostheses
 - o stent, coil, catheter of filter in any blood vessel
 - o ear or eye implant
 - shrapnel, bullets, or other metallic fragments
 - medication releasing skin patches (nicotine, birth control, nitroglycerine)

If you agree to take part in the study, Dr. Spalek and his research team will determine if you meet all relevant conditions to be included in the study. This will be completed with a screening interview, where you will be asked questions about your medical history. Screening should take no more than 15 minutes.

WHAT DOES THE STUDY INVOLVE (PROCEDURES)?

If you are eligible and you decide to participate in this study, you will undergo up to 2 sessions: in one session consists of an MRI scan, and the other session will test your object perception while you receive TMS. The MRI and the TMS sessions will not be performed in the same locations and will occur on separate days. The total duration of your participation in this study will not exceed 2 hours and 45 minutes. Your eligibility for both the MRI and the TMS will first be assessed during a screening interview, which will take about 15 minutes.

If you are eligible for MRI, you will then undergo a high-resolution MRI scan at the Simon Fraser University (SFU) ImageTech Laboratory in Surrey Memorial Hospital. Before your scan, you will be screened again by the imaging personnel to determine whether it is safe for you to undergo MRI. The MRI scan will last about 5 to 10 minutes and the MRI session will last a total of 30 minutes, including screening and set up. The MRI scanner uses a large magnetic field to non-invasively take pictures of your brain. If you are eligible for the MRI scan, this will help the research team guide the TMS stimulation and improve accuracy. If you are not eligible for MRI, we would use a standard brain model instead of your MRI scan to guide the TMS stimulation.

You will then undergo a TMS experimental session at the Spalek Perception Laboratory at SFU's Burnaby campus. TMS involves placing a magnet on the head and applying magnetic pulses which can stimulate the brain. The TMS session will last about 120 minutes. As some time may have passed since the screening interview, we will assess safety and risk concerns with a brief screening questionnaire before starting TMS. If eligible, we will then determine the strength of stimulation that we will use for the experiment. To do this, we will either apply TMS to the visual areas of the brain to measure your *visual threshold*, or we will apply TMS to the area of the brain that controls your hand muscles to measure your *movement threshold*.

Visual Threshold: When TMS is applied to visual brain areas, you may see small spots of light, or you may see a small area of your visual field disappear briefly. Some people may find it difficult to notice these visual changes, so a brief training procedure may be used. For the training procedure, the stimulation intensity is set at a relatively high level to maximize the chances of noticing the visual change. Next, to find the appropriate brain area to stimulate, the stimulation intensity will be decreased to a medium intensity and the magnet will be placed over a few different visual brain areas. Finally, to determine your visual threshold, the stimulation intensity will be decreased to a relatively low intensity and will slowly be increased until you report seeing 5 visual changes out of 10 TMS pulses.

Movement Threshold: Electrode pads will be placed on your finger to measure muscle activity. First, it is necessary to find your "movement hotspot" (i.e., the brain area that produces the strongest finger muscle activity). The stimulation intensity will start low, and gradually increase. Next, the stimulation intensity will be gradually lowered, and your "movement threshold" will be determined to be the stimulation intensity needed to produce 5 muscle activations out of 10 TMS pulses.

After we determine the stimulation intensity, you will be shown images on a computer screen while receiving TMS. In addition to receiving stimulation to the targeted brain area, you will also receive "sham" TMS, where stimulation will be applied to another brain area that is not involved in processing the computer images. You will respond to the images by pressing keys on a keypad. You should not feel alarmed if you find it hard to respond correctly to some of the images. This effect is expected and is short-lasting.

WHAT ARE POSSIBLE HARMS AND SIDE-EFFECTS OF PARTICIPATION?

There are some potential discomforts and risks to your health and well-being if you agree to be a participant in this research. These procedures will be conducted by Dr. Spalek or his research team who have completed procedural and safety training according to published safety guidelines. The potential discomforts and risks are as follows:

Electrode pads:

The adhesive pads used for measuring muscle activity may cause skin irritation or redness. In addition, the alcohol wipes used to clean the skin area for the electrodes may cause irritation.

<u>Computerized Visual Perception Task:</u>

You will be looking at a computer screen, which may cause eye strain. You will also be sitting in a chair for up to one hour, which may cause back and/or leg discomfort for some participants.

MRI:

There is very little risk known to be associated with undergoing an MRI scan. MRI is used routinely in hospitals around the world. A small number of people may find lying still inside the MRI scanner uncomfortable and stressful. If this occurs, you will be brought out of the scanner and the scan stopped. Some people are also uncomfortable being in small places (i.e., claustrophobia). Because the MRI scanner is a small space you may also be uncomfortable lying inside it. If you do feel this way, you will be brought out of the scanner and the scan will be stopped. The MRI also makes loud noises that you may find uncomfortable, but we will use ear plugs to protect your hearing. You will not be able to participate in the MRI portion of this study if you have any metal or surgical implants that may be affected by the strong magnetic fields used in the MRI process or may cause tissue damage associated with dislodging the metal and/or for the objects to become heated during the scan and cause a burn. Most implants are not affected by MRI, but if any of the MRI exclusion criteria listed above apply to you, you will not be able to participate in the MRI portion of this study.

TMS:

The type of TMS stimulation used in this study is considered a safe, non-invasive way to temporarily, and reversibly, change brain activity. Safety standards for the use of TMS have been developed and will be followed by trained operators during this study to minimize the risk. In line with these standards, the TMS machine will always be run at a rate and a frequency that are known to be safe.

A member of the study team has discussed this research with you and has described the risks as follows:

- To the research team's knowledge, there has not been reports of seizures associated with the type
 of TMS you will receive in this study in healthy participants. There is a potential risk of provoking a
 seizure in people with a history of seizures (e.g., epilepsy) or conditions known to increase seizure
 risk (e.g., traumatic brain injury, history and/or conditions.
- Although it is rare, there is a risk of fainting during TMS. This is thought to occur due to anxiety.
 Throughout the TMS session, you will be monitored for any signs of fainting. If you feel that you may faint, the TMS session will be stopped immediately, and you will be assisted. If you have a history of fainting spells, you will not be eligible to participate in this study.
- There is a risk of headache, scalp pain, toothache or scalp numbness associated with TMS. Neck stiffness may also occur, which is thought to be due to holding your head still for a long period of time. Each of these side effects last briefly (usually less than 24 hours).
- The clicks associated with TMS pulses are loud and could potentially damage your hearing. To minimize this risk, you will be asked to wear earplugs throughout the TMS session.

 Although TMS has been performed in laboratories all over the world since 1985, there may be shortand long-term effects that have not yet been identified, and unexpected side effects that have not been previously observed may occur.

WHAT ARE THE BENEFITS TO YOU PARTICIPATING IN THE STUDY?

There is no direct benefit to you for participating in this study. However, it is hoped that the findings from this study will fill gaps in our knowledge and expand our understanding of how the human brain processes important visual information. You will be informed if any significant new findings develop during the course of the study that may affect your willingness to participate in this study.

INCIDENTAL INFORMATION

A potential risk of participating in this study is the discovery of incidental findings during the MRI session, such as brain abnormalities. As this will NOT be a medical scan ordered by a doctor, there will be no formal review of the scans and no report. The MRI scan being done is designed to answer research questions, not examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have found a medical problem in your MRI scan, we will ask a doctor who is trained in the reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and inform you of the abnormality. No information generated in this study will become part of your record routinely. However, if the study detects an abnormality in your MRI scan and further follow-up is required, then this information may become part of your record. If you choose not to be informed of incidental findings on your MRI scan, you will not be able to participate in the MRI portion of this study.

Would you like to	be notified if an abn	ormality is detected	on your MRI scan	? Please check one:
YES	NO			

COMPENSATION TO PARTICIPANTS

Depending on your situation, you may receive money or course credit for your participation.

If you are eligible to receive Research Participation System (RPS) credits, you will receive 1 credit for each half-hour, up to a maximum of 6 credits. Instead of RPS credits, you may receive money in line with hourly minimum wage for your participation time.

WITHDRAWING FROM THE STUDY

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn, for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you want to cancel your enrollment in this study, you can speak to a member of the research team or send a request via email to Dr. Spalek at

<u>tspalek@sfu.ca</u>. If your participation in this study includes enrolling in any optional studies, you will be asked whether you wish to withdraw from those as well.

CAN I BE ASKED TO LEAVE THE STUDY?

If new information related to your health and safety comes to light, the researcher may withdraw you from the study. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

CONFIDENTIALITY

Your confidentiality will be respected. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, including any MRI scans, so that your identity (i.e., your name or any other information that could identify you) as a participant in this study will be kept confidential. Information that contains your identity will remain only with Dr. Spalek and/or his research team. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law. All potentially identifiable data will be destroyed after 2 years. The de-identified data will be stored in a summarized form on a data management service (e.g., SFU Summit) and de-identified MRI scans will be stored on a password protected computer within the Spalek Perception Laboratory until Dr. Spalek retires or moves on from SFU.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study researcher.

QUESTIONS

You have read the information in this form. Dr. Spalek or his research team have answered your question(s) to your satisfaction. You are aware that if you have any more questions after signing this form you may contact Dr. Spalek or one of his associates by email at tspalek@sfu.ca. If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, please contact the Director, SFU Office of Research Ethics, at dore@sfu.ca or 778-782-6593.

PARTICIPANT CONSENT

TITLE: Initial Stages of Visual Processing

Dr. Spalek (or his associates) have given you information about this research study.

They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

My signature on this consent form means:

- I have read and understood the participant information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without being penalized in any way.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I freely and voluntarily consent to participate in this research study. The investigator is satisfied that the information contained in this consent form was explained, that all questions have been answered, and that the participant consents to participating in the research.

I will be given a signed and dated copy of the consent form to keep for my records.

Type/Print Participant's Name		
Signature of Participant	Date	
Type/Print Name of Person Obtaining Consent		
Signature of Person Obtaining Consent	Date	

•	There will be no impact on you if you choose not to take part. You ally future studies in this consent form.	re NOT giving
Are you willing to	contacted in the future about participation in future studies? Pleas	se check one:
YES	NO	
Are you willing to check one:	ow Dr. Spalek and his research team to use your MRI scan for future	e studies? Please
YES	NO	

<u>Future studies:</u> You may be invited to take part in future studies. If Dr. Spalek thinks you might qualify for another study by him or his colleagues, he will contact you directly by email or telephone and ask if