COMPOUND AUTHORIZATION & CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE
CONNECTICUT MENTAL HEALTH CENTER (CMHC)
THE BELIEF, LEARNING, & MEMORY LAB (BLAM)

Study Title: Neurocomputational Models of Auditory Hallucinations (Aim 1)

Principal Investigator: Philip Corlett, PhD
34 Park Street
New Haven, CT 06519
(203)974-7866
philip.corlett@yale.edu

Funding Source: National Institute of Mental Health (NIMH)

Invitation to Participate & Description of Project

You are invited to take part in a research study designed to look at how magnetic stimulation of the brain affects behavior. You have been asked to take part because you are someone with lived experience hearing voices or other things that others do not experience; you have never experienced a seizure, neurological illness, or head injury. The research will take place at Yale University. We expect that up to 30 people will take part in this study.

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 study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research including its purpose, the procedures that will be performed, and the risks of those procedures. Once you understand the study, you will be asked if you wish to participate. To participate in the study, you will be asked to sign this form.

Description of Procedures

If you agree to take part in this study, you will be asked to undergo Transcranial Magnetic Stimulation (TMS) procedures over 3 visits. A magnet will be placed on your scalp. The magnet is turned on by sending an electrical current through it. The magnet will transmit magnetic waves into different parts of your brain. It will make a loud sound. We will measure your hearing before and after the procedure and we will give you earplugs to protect you from hearing damage. We are hoping to find out if this procedure, can interrupt, change, or lessen your brain responses and behavior.

APPROVED BY THE YALE UNIVERSITY IRB 6/14/2021

Figure-of-eight transcranial magnetic stimulation (TMS) is a focal, non-invasive form of brain stimulation that can increase or decrease the responses of nerve cells in the human brain (See Figure 1). TMS typically involves positioning an electromagnetic coil on the scalp. This coil uses electrical current to create powerful but brief magnetic fields that enter the brain obstruction. Electrical energy in the TMS coil is transformed into magnetic energy that travels across the skull. This magnetic energy is converted back into electrical energy in the brain.

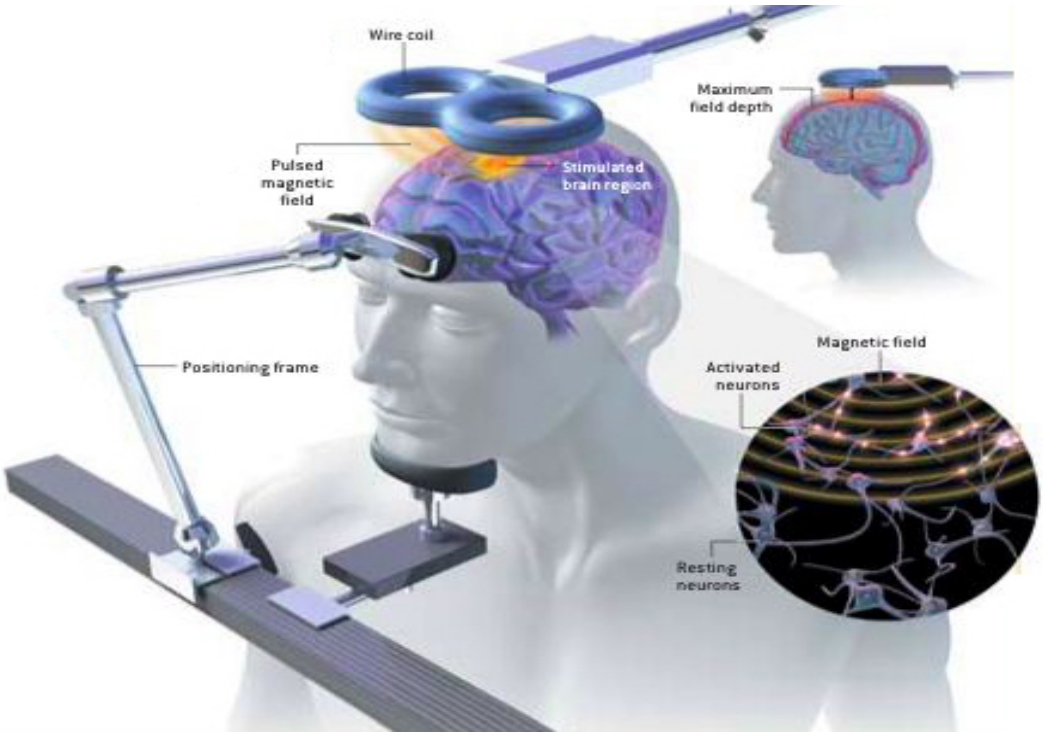

FIGURE 1: A diagram of how TMS use (adapted from (George 2003)).

Before receiving magnetic stimulation, you would undergo a test to determine the strength of the stimulation. This will be done by using the electromagnet to stimulate a part of your brain that controls finger movement. We will monitor muscle contractions with recording electrodes (similar to the ones used for the EKG) placed on your right thumb and index finger. The amount of magnetic stimulation needed to produce slight muscle contractions will guide us in determining the level of magnetic stimulation to the part of the brain that may produce voices.

Magnetic stimulation can cause muscles in your scalp or jaw to contract. This sensation generally is not painful but may be uncomfortable or mildly painful. It stops as soon as the magnetic stimulation stops. If the stimulation is too uncomfortable, we will shift the position of the magnetic stimulator on your scalp. If the stimulation remains too uncomfortable, we will reduce the strength of the magnetic stimulation. We can offer a gum shield to lessen the effects of the TMS on your jaw, if you like.

Right after the stimulation, we will ask you to complete a computer game. While wearing headphones, you will guess whether or not a tone was played. We will also ask you how confident you are in your choices.

Across the 3 visits, you will receive either one pattern of stimulation, a different pattern of stimulation, or a sham stimulation (no magnetic field). The order of active and placebo stimulations will be determined randomly.

The active and sham stimulation procedures with be conducted for about 20 minutes. The effects can last up to one hour, although it's unlikely you will notice them.

The amount and pattern of stimulation you receive is within current FDA guidelines and published guidelines from experts in the field.

Immediately after each stimulation session, we will ask you to complete some tests of learning, memory, concentration, and perception on a computer screen. The tests will last for about 40 minutes.

The sham and simulation visits will be separated by at least a week and each will take about 2 hours, from start to finish.

If you sign the consent form today, we will ask you some questions about your physical and mental health to make sure that it is safe and appropriate for you to take part. We may ask for the contact information of a friend or family member to confirm the information that you give us in the interview. This is to make certain that we have all of the correct information as we decide whether it is safe and appropriate for you to take part in the study.

We may ask for a urine sample to test for illicit drug use. If you use illicit substances, you will not be able to take part. If you are a female, we will ask you to complete a pregnancy test. If you are pregnant, you will not be able to take part in the study.

We will also be collecting a blood sample. We will draw no more than 30ml or 2 tablespoons of blood. Routine lab work will be completed to make sure it is safe for you to participate in this study.

You will be told if any significant new findings are developed during your participation in this study that may affect your willingness to continue to participate.

At the end of the three study visits, you will have the opportunity to discuss the study procedures with the study team.

Risks & Inconveniences

The blood draw may be uncomfortable or painful. You may have a bruise or be sore at the site where blood is drawn.

Transcranial magnetic stimulation has been observed, in rare instances, to cause a seizure. In most but not all of these cases, the patient had a history of seizures in the past. Taking

antipsychotic mediations and being on multiple medications may also increase seizure risk Therefore, there is a small risk that the magnetic stimulation could cause a seizure in your case. It is very important that you let us, the study team, and in particular the study doctor know if you have ever had a seizure at any time in your life. If you do have a seizure during the study, you will be taken to the Yale – New Haven Hospital emergency room for checking and possible treatment.

A potential side effect is temporary hearing loss due to the loud sound that the stimulation machine makes. The loudness of the sound is approximately 140 decibels, which is about as loud as the sound of a door slamming from across a room. We will give you earplugs and cushioned, plastic earmuffs to wear to reduce the risk of temporary hearing loss, in previous studies hearing changes were rare and resolved within 4 hours from the end of stimulation. We will give you ear plugs in your inner ear during the stimulation to protect against any possible hearing damage. We will also test your hearing before and after the stimulation.

Following the stimulation sessions, you may experience a mild headache. These headaches typically respond to medication like Tylenol or Motrin.

You may also feel dizzy or nauseous. Please tell us if you do. We will stop the stimulation and observe you until these side effects subside. If they occur, they typically only last a few minutes after the stimulation stops.

If your hearing changes or if the effects of stimulation are too unpleasant, you can stop the stimulation at any time. If you stop, you will not be asked to return for the follow-up session.

There may be additional risks related to this study that are not yet known.

Benefits

The study will not benefit you directly. The knowledge we gain by conducting the study may benefit those with psychiatric or neurological illnesses in the future.

Economic Considerations

You may be paid up to $200.00 for completing the study. This would include

- $50 for the screen today and
- $50 for each of the 3 study visits.

According to the Internal Revenue Service (IRS), payments that are made to you because of your participation in a study may be considered taxable income.

Alternatives

The alterative to participation is not to participate.

Confidentiality & Privacy

Any of your identifiable information that is collected in connection with this study will remain confidential and will be disclosed only with your permission or as permitted 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. Data will be coded with ID numbers instead of using your name. The study team will take care to link the data with your name only during acquisition and to break that link as soon as practically possible. Research materials will be kept in locked cabinets. Computerized data will be password protected. 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.

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 receive information that identifies you and information about your personal health. This may include information that might directly identify you, such as your name and contact information (including your telephone number, e-mail address, etc.). This information will be de-identified at the earliest reasonable time after receiving 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. This link will be kept secure and available only to the PI and selected members of the research team. Any information that can identify you will remain confidential. Research materials will be kept in locked cabinets. Computerized data will be password protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, 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:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Diaries and questionnaires
- The diagnosis and treatment of a mental health condition
- Use of illegal drugs
- Records about the study device

Information about you and your health which might identify you may be used by or given to:

- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. 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
- The Principal Investigator: Philip Corlett, PhD
- The Independent Safety Monitor (ISM): Rachel Katz, MD
- Co-investigators and other investigators
- Study Coordinator and members of the Research Team
- The U.S. Department of Health and Human Services
- The funder: National Institutes of Mental Health

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 Connecticut Mental Health Center 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 and/or companies that require that they keep your information confidential.

If you decide to be in this study, you will be visiting the Connecticut Mental Health Center (CMHC) as part of your study procedures. Some information about your participation in this research study will become part of your CMHC medical record that identifies you. If you do not already have a medical record at CMHC, one will be made for your visit. The information that will be entered into your medical record will include the following:

- Information about your physical health
- Information about your mental health (diagnosis, current symptoms)
- Dates of study visits
- Progress notes regarding the study

This authorization to use and disclose your health information collected during your participation in this study will never expire.

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 participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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

In Case of Injury

Although it is very unlikely that you will be injured by participating in this study, if you are injured while on study, please seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and the Connecticut Mental Health Center do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. 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 & 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, 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 participant, you are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can contact a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary. For example, if you have an unexpected response to TMS or you find it difficult to comply with the study procedures.

Withdrawing from the study will not result in any penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with the Connecticut Mental Health Center (CMHC).

Withdrawing Your Authorization to Use & 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 the Principle Investigator:

Philip R. Corlett, PhD
Yale University Department of Psychiatry
Connecticut Mental Health Center
34 Park Street
New Haven, CT 06519
philip.corlett@yale.edu

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. 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.

Questions

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

Authorization & Permission

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.

Participant - Printed Name	Participant - Signature	Date

Person Obtaining Consent - Printed Name	Person Obtaining Consent - Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact:

Yale Privacy Officer
(203)432-5919
hipaa@yale.edu

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator*:*

Philip Corlett, PhD
Yale University Department of Psychiatry
Connecticut Mental Health Center
34 Park Street
New Haven, CT 06519
(203)974-7866
philip.corlett@yale.edu

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 participant, you may contact:

Yale Human Investigation Committee
(203)785-4688
HRPP@yale.edu

Future Research (Optional)

The researchers at Connecticut Mental Health Center (CMHC) and the Belief, Learning, & Memory (BLAM) Lab will continue to do research designed to lead to a better understanding of people who hear voices and new treatments for them. If you wish to participate in any upcoming studies, these researchers can contact you in the future. By signing this form, you will allow researchers to contact you in the future to ask if you want to participate in any studies. You have **no obligation** to actually participate in any study. You **do not** have to agree to future contact to participate in the current study.

Can researchers contact you in the future about new study opportunities? ☐ YES ☐ NO

_____	_____	_____
Participant - Printed Name	Participant - Signature	Date

Contact Information:

Email: _____

Mobile Phone: _____ Mobile Carrier: _____

Can we leave a voicemail? ☐ YES ☐ NO

Can we send a text? ☐ YES ☐ NO

Home Phone: _____

Can we leave a voicemail? ☐ YES ☐ NO