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Protocol Number: 2018P-000603

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
09/13/2021
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: The Development and Human Translation of Temporal Interference Brain Stimulation
PRINCIPAL INVESTIGATOR: Daniel Press, MD
PROTOCOL NUMBER: 2018P-000603

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Daniel Press, MD and is funded by the National Institutes of Health (NIH). The funding agency in this study, the NIH, is paying Beth Israel Deaconess Medical Center Dr. Press to perform this research. BIDMC or Dr. Press has/have no additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Press at [617] 667-0459.

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PURPOSE

The main purpose of this study is to test a new way of doing brain stimulation using ***Temporal Interference (TI)*** and to test the safety of this type of stimulation***.*** TI is a noninvasive way of stimulating the brain using a mild electric current. In this study, the goal is to do the TI in a way that it stimulates a focused (small) area in the brain – specifically the visual area. It is known that stimulating the visual area of the brain can cause brief visual changes that are transient (they don't last). This is how we will test if the stimulation to the focused brain area works. TI works as follows:

- External electrodes (small pads) will be placed on your head
- A weak electrical current will travel through the electrodes and will stimulate your brain

This study also includes magnetic resonance imaging (**MRI**) – a method of taking pictures of your brain using a large magnet and radio signals. The MRI will be used to identify areas of your brain related to vision that we will stimulate. This will involve doing a visual task and then undergoing an MRI while doing the visual task again. ***The MRI scan for this study will be done at Boston University (BU) and is required in order to continue in the study. There will be a separate consent form at BU for this part of the study that will review the details of the visit further.***

The TI device involved in this study is investigational. This means that the study device is still being tested in research studies and is not approved by the Food and Drug Administration (FDA).

STUDY PARTICIPANTS

You have been asked to be in the study because you are a healthy volunteer. Approximately 20 people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. The screening will take approximately 1.5 hours. For this research study, the screening procedures include:

    - An exam by a doctor or nurse practitioner
    - A review of your medical history and medications
    - A baseline measurement of your vision – for this assessment, your head will be positioned against a forehead and chinrest. You will be asked to look at a central target and respond when a light stimulus is noted. One eye will be tested at a time

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while the other eye is patched. Due to time constraints, this measurement may be completed after the MRI visit at BU.

You will be asked to:

- Answer questions about your demographics, for example your age and years of schooling
- Answer questions to see if it is safe for you to have an MRI and TI. For example, you will be asked if you have any metal in your body or if you have a history of seizures.
- Answer questions about your mood and feelings
- Practice for the visual task that you will be asked to do with the MRI – this involves focusing your vision on a fixed spot

Additionally, we will:

- Have you provide a urine sample for a pregnancy test if you are a woman able to become pregnant

The screening procedures will occur in 1 visit and will take approximately 1.5 hours.

If you agree to participate in this study and qualify, we will share your information with the study team at BU (such as your name, date of birth, screening) in order to schedule and plan your MRI visit. All of the information collected at the MRI visit will be shared with us in order to conduct the study. Information that we collect in study visits at BIDMC may be shared with the researchers at BU for analysis.

2. Research Procedures: Once you have completed the MRI study at BU, you will return to BIDMC for the stimulation study visits. There will be up to 4 visits with a minimum of 2 visits that you will be asked to do. You will undergo these research procedures at each visit:

- You will sit in front of a screen and complete a visual discrimination task. You will be asked to look at a specific spot and report on what you see by pressing a button. On the first visit, the study staff will review the training with you and give you instructions.

- We will place a cap or headband on your head with electrodes that have gel in them. The electrodes in the cap will deliver stimulation.

- You will receive stimulation for 10 minutes or less
    - You will be asked to do the visual discrimination task again during the stimulation
    - You may be asked to look at a grid and note if you notice any changes in your vision during the stimulation – it is anticipated that you might notice some visual effects during the stimulation such as phosphenes (brief flashes of light similar to those seen when you press on your eye), or a scotoma (an inability to see visual

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stimuli in specific locations). This is a known transient effect of stimulation to the visual area of the brain and is expected to go away after the visit.

- When the stimulation stops, you will be asked to do the visual discrimination task again
- You will have a break
- The above steps may be repeated 3 more times (e.g. task, stimulation with task, task) with breaks between each time

At the end of each visit, you will repeat the eye test that you had at your screening visit.

You will be asked questions about any adverse effects at the beginning and the end of each session. Each stimulation visit will last for approximately 3 hours.

DATA SHARING

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers to collect and share de-identified information with each other. As part of your participation in the study, a unique subject number will be assigned to you that will allow researchers to see if you have been involved in more than one research study or database such as the NDA described above. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators. This unique subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you.

You may decide now or later that you do not want to share your information using NDA. If you agree now and change your mind later, contact the researchers who conducted this study (see the "Whom to Contact" Section above), and they will tell NDA, which can stop sharing the research information. However, we cannot take back information that was shared before you changed your mind.

☐ I ***agree*** to share my de-identified data in the NDA	☐ I ***do not agree*** to share my de-identified data in the NDA

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RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Risks of TI

More Common

- Sensations under the electrodes
  - 20-70% of participants undergoing electrical stimulation felt sensations under the electrodes such as tingling or itching.
  - 10-20% of participants feel discomfort such as mild pain or burning.

  These sensations usually resolve shortly after the start of stimulation. We turn the stimulation on slowly to keep these sensations to a minimum.

- Skin Irritation
  - The electrodes used may cause skin irritation or redness (30%)

- Other common side effects include:
  - Moderate fatigue (35%)
  - Headache (10-15%)
  - Difficulties in concentration (11%)

Less Common

- Nausea or Nervousness (<5%)
  - If you feel Dizzy, Lightheaded, or that you might vomit, the study will be stopped.

Rare

- Seizure
  - A seizure is theoretical. It has never been observed in research studies involving electrical stimulation, but it is possible.
  - A seizure is a convulsion where a person's body shakes. If you have a seizure, we have emergency equipment and you will receive immediate medical care.
- A change in mood has occurred in people with bipolar disorder or depression. You will not be included in the study if you have a history of a psychiatric disorder.
- Muscle twitching or tingling sensation on your body.
- Ringing in the ear (<1%)
- Transient visual disturbance (2%)
  - Some participants have reported a sensation of feeling as if their vision is shaking or moving during the stimulation. This has gone away when the stimulation is stopped.

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Pregnancy
Due to the extremely small but potential risk of a seizure from stimulation, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before stimulation will be applied.

Furthermore, if you are a woman capable of becoming pregnant, you must agree to use adequate birth control. For the purpose of this study, use of adequate birth control includes one of the following:

1. oral hormonal contraceptives;
2. implanted hormonal contraceptives
3. diaphragm with spermicide;
4. condoms;
5. Intra-uterine device;
6. abstinence.

Risks associated with baseline questions
Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time.

Visual Testing:
You may feel frustrated during the visual tasks and testing. You will have breaks between the tasks to reduce the potential for frustration.

Electroencephalography (EEG):
EEG is a safe and painless procedure for most people. You may experience some scalp irritation from the electrodes. If this happens, it will last a short time (a day or two).

Loss of Confidentiality
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

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CERTIFICATE OF CONFIDENTIALITY

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information or specimens that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing your information or specimens if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or for use in other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. By signing this form, you are giving your consent to the disclosure of your information or specimens for any purpose you have agreed to in this informed document and for any purpose permitted without additional authorization in the BIDMC Notice of Privacy Practices. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information or specimens, then the researchers are permitted, but not necessarily required, to disclose that information.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the option of not participating in the study.

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This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for the baseline medical assessments; eye exams; or TI that are part of this research study.

PAYMENTS TO YOU:

For your participation in this study, you will be paid $30 per hour for each baseline visit and $45 per hour for each study visit with stimulation. If you withdraw from the study, which you can do at any time, you will only be paid for the study visits that you have completed. You will be paid after you have completed the screening and the first two stimulation visits. If you complete the additional two stimulation visits, you will be paid for those after you have completed both visits.

It may take up to 8 weeks for you to receive payment by check.

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Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

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PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The funding source and/or sponsor of this study, the National Institutes of Health (NIH), and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share

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your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Daniel Press at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____