University of California, San Diego
Consent to Act as a Research Subject

Cognitive Brain Stimulation for Depression

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
This is a research study being conducted by Dr. Jyoti Mishra at UCSD. Research studies include only subjects who choose to take part. You are being asked to take part in this study because you are at least 18 years old and you have been prescribed standard-of-care transcranial magnetic stimulation (TMS) for treating depression at the UCSD Interventional Psychiatry clinic. There will be approximately 104 total participants in this study. This is one of two sites in the study and each site will enroll approximately 52 participants. Please take your time to make your decision. Be sure to ask any questions that you may have.

Why is this study being done?
The purpose of this study is to evaluate how combining your prescribed standard-of-care TMS treatment with a breath-oriented cognitive exercise affects brain function and mood. The long-term purpose of this study is to improve understanding of mental wellbeing and treatment of mental disorders.

What will happen to you in this study and which procedures are standard of care and which are experimental?
If you agree to be in this study, you will receive your prescribed standard-of-care TMS treatment for 30 sessions. The "experimental" part of this study is that while you receive TMS and for 20 minutes after your receive TMS at each session, we will request you to do breath-oriented cognitive exercises on a computer tablet provided to you. Additionally, we will request you to complete mental health surveys as well as assessments of brain and cognitive function before and after your full TMS treatment.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?
It will take approximately 15 minutes to explain the study procedure and get your participant consent. We will ask questions about your family background, sleep, alcohol/drug use, physical exercise, as well as questions about your mental health, including thoughts and feelings of anxiety, and depression. These assessment will be conducted by research staff online and by phone and will take approximately 2 hours.

After this, at the time of your first scheduled TMS visit at the clinic, right before the TMS session, we will ask you to engage in about 1 hour of game-based brain and cognitive assessments on a computer. While engaging with the cognitive assessments, your brain activity will be measured with EEG (electroencephalography). For this measurement, you will sit on a chair and wear a cap that allows us to collect information about electrical signals produced by different parts of your

brain. If you agree, we will also measure cardiac and respiratory signals simultaneous with the cognitive and EEG measurements that tell us about your heart function and breathing, respectively.

You will then engage in 30 days of your prescribed standard-of-care TMS treatment coupled with the breath-oriented cognitive exercises; daily sessions will last approximately one hour including breaks. You will also be asked to complete weekly online mood questionnaires, which will take 10 minutes to complete at the end of each week.

At the end of the full TMS treatment for 30 days, you will again participate in the mental health surveys as well as assessments of brain and cognitive function that you did before starting your TMS treatment for approximately 2 hours.

Finally, at 6 weeks and 12 weeks after your TMS treatment, we will ask you to complete the online mood questionnaire again, which will take 10 minutes to complete each time.

What risks are associated with this study?
Side effects may include:

- tiredness or mild to moderate demands on attention and cognition during the cognitive exercises and behavioral assessments.

Side effects seen less often include:

- feelings of anxiety.
- mild physical discomfort because of the tight fit of the EEG cap.
- mild physical discomfort because of the cardiac and/or respiratory sensors.

If you feel any of these things, or other things, be sure to tell the research staff.

Other risks in this study include the following:

- You may experience worsening of mental health symptoms during or after this study. The research staff will periodically ask you a set of questions to assess your current mood. You can always decide to not participate further if you feel worse.
- There is minimal risk of breach of privacy due to the electronic data collection. The software we use is specifically developed for academic research, the server is password protected, your personal information will be stored separately from the study data, and the study data will be identified only by a study ID. Nonetheless, there is still a risk, despite these precautions, of a loss of confidentiality. If any breach/security issues are identified, you will be informed.
- Because this is a research study, there may be some risks, which are not yet known.

For more information about these risks and side effects, ask your study doctor.

What are the alternatives to participating in this study?
The alternatives to participation in this study are not to participate. Your decision to participate in this study will not affect your eligibility to receive standard-of-care TMS.

What benefits can be reasonably expected?
You may or may not have added benefits from this study compared to standard-of-care TMS alone, although you may experience a positive change in mental health with repeat sessions. The investigators may learn more about the nature and treatment of mental health conditions based on brain function.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you may do so with no negative effects, and simply by informing the research staff conducting the experiment.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

Dr. Jyoti Mishra believes it is in your best interest to not continue with the study.
You feel pain/discomfort at any point throughout the study.
You no longer wish to participate in the remainder of the study.

You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
In compensation for your time and travel, you will receive $200 at the end of the study. The compensation will be given in the form of e-gift cards to retailers (e.g. Amazon).

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. This also means we do not share information you give.

While you are participating at the clinic, you are authorizing the researchers to access the medical record to obtain limited information about your medical diagnosis and medications, which will be de-identified.

Under California law, the only exceptions to this privacy rule are: 1) if you express suicidal

thoughts or plans, the confidentiality may need to be broken to help you; 2) We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities.

Risks to privacy will be minimized by de-identifying all measurements and individual test results and treating them confidentially. Written informed consent/assent and minimum identifying information collected from participants will have separate secure, HIPAA-compliant, electronic locations from the securely stored de-identified study data so that individuals cannot be easily connected to the study results. Research records may be reviewed by the UCSD Institutional Review Board.

Who can you call if you have questions?
Dr. Jyoti Mishra and/or an authorized research staff personnel has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Jyoti Mishra at (858) 232-2855.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Subject's signature Date

_____ _____
Signature of Witness (person explaining this form) Date