Informed Consent: Repetitive Transcranial Magnetic Stimulation

Introduction

Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive method of applying magnetic stimulation to the brain for therapeutic benefits. The U.S. Food and Drug Administration (FDA) has cleared specific devices that deliver rTMS for use in adults with 1) Major depressive disorder (MDD) who have failed to receive satisfactory improvement from antidepressant medications and 2) Obsessive-compulsive disorder (OCD). Using TMS for conditions other than treatment-resistant MDD and OCD is considered "off label" at this time. In the United States, physicians are permitted to use FDA-cleared medical devices and medications for "off-label" purposes if they believe it is safe and reasonably expect that such use will benefit their patients. Treatment with the magnetic stimulation device is investigational if used outside of the FDA-cleared intended use. Our use of the magnetic stimulation device for your rTMS treatment is investigational.

Approach

Sleep and Brain uses personalized rTMS (PrTMS). Unlike conventional rTMS, PrTMS is tailored to each individual's medical assessment. During a PrTMS session, you will be led to a treatment room and seated in a comfortable chair in a slightly reclined position. A member of the care team will place an electromagnetic coil softly against your head. The coil painlessly delivers a magnetic pulse that stimulates nerve cells at predetermined intervals throughout a session of approximately thirty minutes. We determine the exact treatment protocol for you based on your initial medical assessment results, which will have included discussions of your current medical condition, medical history, results of neurocognitive tests, and a quantitative EEG of your brain waves. Our PrTMS therapy typically consists of five thirty-minute sessions per week for six to eight weeks.

In general, PrTMS individuals are re-evaluated after every five PrTMS treatments to determine whether adjustments are needed. Adjustments intended to improve patient response or safety are based on testing and the information we receive from you regarding your treatment response. Therefore, you must tell us how you feel, answer our questions honestly, and disclose underlying medical conditions to make our best medical judgment. Before beginning treatment, your medical provider will review the contraindications and precautions to rTMS use in the context of your medical history. You must update us if there are any changes to this information after your treatment begins.

Risks

Unlike vagus nerve stimulation or deep brain stimulation, rTMS does not require surgery or implantation of electrodes. And, unlike electro-convulsive therapy, rTMS rarely causes seizures or requires sedation with anesthesia. TMS does not require pharmaceutical products, avoiding side effects associated with drug consumption. rTMS may take a few weeks before symptom improvement occurs. However, not everyone responds to rTMS. There is a possibility that rTMS will not be effective for you and may worsen your symptoms. You must report worsening symptoms immediately to your physician. You understand that it is advisable to have a family member or caregiver monitor and identify worsening signs. Generally, rTMS is considered safe and well-tolerated.

Adverse effects
Common side effects may include headache, scalp discomfort at the stimulation site, and lightheadedness. Other side effects may include jaw pain, muscle twitching, nausea, vomiting, anxiety, agitation, back/neck pain, tinnitus, migraine, abnormal sensations, mood instability, and insomnia. Rare, serious side effects may include seizures, mania, or other psychosis. You understand that you should inform your doctor if you experience any adverse events.

Alternatives to rTMS
While my doctor has recommended PrTMS for me, I understand that other treatment options exist, such as medications, psychotherapy, vagus nerve stimulation, and electro-convulsive therapy. Which treatment option is right for me depends on multiple factors, including but not limited to previous experience, the severity of my disorder, potential side effects, and other factors and risks. My medical provider has explained to me why PrTMS may be helpful for my specific case.

Contraindications
rTMS should not be used by individuals with 1) implanted electronic devices that are activated or controlled by physiological signals (e.g., deep brain stimulation, cochlear implants, and vagus nerve stimulators) and 2) conductive, ferromagnetic or other magnetic-sensitive metals implanted in the head or within 12 inches of the treatment coil (e.g., cochlear implant, implanted electrodes/stimulators, aneurysm chips or coils, stents, and bullet fragments). Contraindicated use could result in serious injury or death. *Standard amalgam dental fillings are safe.*

Precautions
- Individuals with diabetes, history of stroke, alcohol influence, and hypnotic use who are at an increased risk of thermal injury due to an impaired ability to sense heat or pain.
- Individuals with neurological conditions, including a history of seizures, cerebrovascular disease, dementia, movement disorders, increased intracranial pressure, or primary or secondary CNS tumors.
- Individuals with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices, and stents.
- Individuals with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers and implantable cardioverter defibrillators.
- Individuals with a history of increased intracranial pressure or head trauma.
- Individuals with a history of epilepsy or unexplained seizures.
- Individuals medicated with drugs lowering the seizure threshold (e.g., neuroleptic agents and tricyclic antidepressants).
- Individuals medicated with drugs enhancing the effect of the neurotransmitter gamma-aminobutyric acid.
- Individuals suffering from vascular, traumatic, tumoral, infectious, or metabolic lesions of the brain, even without a history of seizure, or without anticonvulsant medication.
- Individuals with a history of head injury, severe headaches, or repetitive or severe head trauma.
- Individuals with severe or recent cardiac disease.

- Individuals with an unstable medical illness.
- Pregnant or nursing individuals.
- Individuals who drink alcohol must avoid drinking alcohol 24 hours before treatment.

Patient Consent to rTMS Therapy
You understand that you are free to ask your medical provider questions about PrTMS at any time before, during, or after the course of your treatment. You understand that you are voluntarily deciding to receive PrTMS therapy and may withdraw your consent and terminate the treatment at any time. You have read (or have had it read to me) the information contained in this consent form about PrTMS therapy and its potential risks and benefits for the treatment of your diagnosis of:

Informed Consent for rTMS
My medical provider has explained the risks and benefits of PrTMS therapy and the other treatment options for my condition. The provider has answered all questions regarding PrTMS treatment to my satisfaction. If during treatment, situations arise that require emergency treatment in the best judgment of the care team, I authorize and request performing that said treatment. I understand that individual results vary and that no guarantee, warranty, or assurance of any results obtained from PrTMS therapy or promise of cure, amelioration, or remission of any disease or condition has been made to me either verbally or in writing.
I have read the information in this Medical Procedure Consent Form about PrTMS treatment, the process involved in the treatment, and its potential risks. I understand the other treatment options the doctor discussed with me. My doctor has reviewed rTMS contraindications and precautions and has answered all of my questions. I know that I can ask questions about PrTMS at any time before, during, or after the course of treatment and that I may discontinue therapy at any time. I consent to the PrTMS treatment and related procedures, and I authorize and request that my medical provider and Sleep and Brain care team administer a course of PrTMS therapy to me. I have read (or have had it read to me) this Informed Consent printed in English. English is a language that I can read and understand. I am signing and agreeing to all aspects of this consent form as the: ☐ Patient ☐ Guardian

Patient Name	Patient or Guardian Signature	Date
Physician Name	Physician Signature	Date
Witness Name	Witness Signature	Date