



Patient Consent for Transcranial Magnetic Stimulation (TMS Therapy)

This is a patient consent for a medical procedure called TMS Therapy. This consent form outlines the treatment that the doctor has prescribed for you, the risks of this treatment, the potential benefits of this treatment to you, and any alternative treatments that are available for you if you decide not to be treated with TMS Therapy.

Once you have reviewed this consent form, be sure to ask any questions you may have about TMS Therapy and its use in treating depression.

The following information has been explained to me:

- a. TMS stands for “Transcranial Magnetic Stimulation”. TMS Therapy is a medical procedure. A TMS treatment session is conducted using a device which provides electrical energy to a “treatment coil” or magnet that delivers pulsed magnetic fields. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.
- b. TMS Therapy is an FDA-approved treatment for patients with depression who have not benefitted from antidepressant medications and is considered safe and effective.
- c. Specifically, TMS Therapy has been shown to relieve depression symptoms in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
- d. During a TMS treatment session, the doctor or a member of their staff will place the magnetic coil gently against my scalp. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists have proven may be responsible for causing depression. To administer the treatment, the doctor or a member of their staff will first position my head appropriately. Once treatment begins, I will hear a clicking sound and feel a tapping sensation on my scalp. The device will be adjusted by the doctor and will give just enough energy to send electromagnetic pulses into my brain so that my right-hand twitches. The amount of energy required to make my hand twitch is called the “motor threshold”. Everyone has a different motor threshold, and the treatments are given at an energy level that is just above my individual motor threshold. How often my motor threshold will be re-evaluated will be determined by my doctor and depends on my initial response to the treatment.

- e. Once motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of “pulses”. Treatment will take about 20 minutes, unless I elect to receive TMS therapy theta burst treatments which may last approximately 3-minutes or another treatment protocol, which will have been explained to me. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. For optimal results, I will receive 5 treatments per week for 4 to 6 weeks (up to 36 treatments) for treatment sessions lasting approximately 20 minutes for the treatment of depression. For theta burst treatments or treatment protocol, my doctor has explained the number of treatments I should receive, as every patient may respond differently. My response to the treatment may likely be evaluated by the doctor one to two times during treatment.
- f. During the treatment, I may experience a tapping sensation at the treatment site while the magnetic coil is turned on. I understand this '*tapping*' may be uncomfortable for me, and for some people, may be perceived as painful. I understand that I should inform the doctor or his/her staff if unable to tolerate the '*tapping*'. The doctor or technician may then adjust the dose or make changes to where the coil is placed to help make the procedure more comfortable for me. I also understand that I may experience a headache after treatment. I understand that both discomfort and headaches are a potential side effect but often lessen over time. I may take over-the-counter medication if a headache occurs.
- g. The TMS Therapy System should not be used by anyone who has:
- 1) Magnetic-sensitive metal in their head or within 12 inches (30 cm) of the magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. These include but are not limited to:
 - Cochlear implants
 - Aneurysm clips or coils
 - Stents
 - Electrodes to monitor your brain activity.
 - Ferromagnetic implants in your ears or eyes
 - Bullet fragments
 - Other metal devices or objects implanted in the head.
 - Facial tattoos with metal ink or permanent makeup

2) Implanted stimulators in or near the head. These may include:

- Deep brain stimulators
- Cochlear implants
- Vagus nerve stimulators
- The TMS Therapy System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators (or are using wearable cardioverter defibrillators (WCD). Failure to follow this restriction could result in serious injury or death.

- h. TMS Therapy is not effective for all patients with depression. Any signs or symptoms of worsening depression should be reported immediately to your doctor. You may want to ask a family member or caregiver to monitor your symptoms to help you spot any signs of worsening depression. It is important to note that during the first 2 weeks (especially over the first couple of weekends - Saturday/Sunday) you may feel '*more down than usual*' as the treatment begins to work.
- i. While very rare, seizures have been reported with the use of TMS devices. The estimated risk of seizure under ordinary clinical use is approximately 1 in 30,000 treatments or 1 in 1000 patients.
- j. Because the TMS Therapy system produces a loud click with each magnetic pulse, I understand that I should wear earplugs with a rating of 30dB or higher or sign a waiver to decline hearing protection devices during treatment.
- k. I understand that most patients who benefit from TMS Therapy experience results by the fourth week of treatment. Some patients may experience results in less time while others may take longer.
- l. I understand that symptom relief from TMS Therapy may be lost over time, and I will need to take antidepressant medication to help retain symptom relief. I understand that approximately one-third of patients require re-treatment TMS Therapy in approximately six to eighteen months, as I acknowledge that every patient responds differently. New research indicates that periodic maintenance treatments or annual treatments optimize symptom relief, and thus offers longer remission periods from depression.
- m. I understand that I may discontinue treatment at any time.

I have read the information contained in this Medical Procedure Consent Form about TMS Therapy and its potential side effects and/or risks. I have all my questions answered. I understand there are other treatment options for my depression available to me, such as medications and psychotherapy and this has also been discussed with me.

I therefore permit Dr. _____ and his/her Certified TMS Therapy staff to administer TMS therapy treatment to me.

PATIENTSIGNATURE

DATE

PATIENT NAME (PRINTED)

WITNESS SIGNATURE (TMS EMPLOYEE)

DATE