

PATIENT CONSENT FOR A MEDICAL PROCEDURE - TRANSCRANIAL MAGNETIC STIMULATION (TMS)

This is a patient consent for a medical procedure called TMS Therapy. This consent form outlines the treatment that your 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. The doctor has explained the following information to me:

1. A TMS treatment session is conducted using a device called a TMS Therapy System which provides electrical energy to a treatment coil that delivers pulsed magnetic fields. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.
2. TMS Therapy FDA cleared and considered to be a safe and effective treatment for patients with depression who have not benefitted from antidepressant medications.
3. TMS treatment does not involve any anesthesia or sedation so I will remain awake and alert during the treatment.
4. During a TMS treatment session, the doctor and/or a staff member 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 believe maybe responsible for causing depression.
5. To administer the treatment, the doctor and/or staff member will first position my head in the head support system. Next the magnetic coil will be placed on my head, and I will hear a clicking sound and feel a tapping sensation on my scalp. Adjustments are then made so that the device will give just enough energy to send electromagnetic pulses into the brain so that my 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. My doctor may re-evaluate and adjust the motor threshold at times during the course of my TMS Therapy.
6. Subsequent daily TMS treatments involve a series of "pulses" that last about 4 seconds, with a "rest" period between each series. Daily treatment will take about 19-60 minutes depending on my individual treatment parameters. I will receive these treatments 5 times per week for 6 weeks (30 treatments). A taper phase and/or maintenance schedule maybe recommended once my initial treatment period is completed.
7. During the treatment, I may experience tapping or painful sensations at the treatment site. I understand that should inform the doctor and/or staff if this occurs. The doctor and/or staff may then make adjustments to help make the procedure more comfortable for me. I also understand that headaches were reported in some patients who participated in the TMS Therapy clinical trials. I understand that both scalp discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications if needed.
8. TMS Therapy should not be used by anyone who has magnetic-sensitive non-removable metal in their head or within 12 inches of the magnetic coil of the TMS Therapy System. Failure to follow this restriction could result in serious injury or death. Objects that may have this kind of metal include: aneurysm clips or coils, stents, implanted Stimulators, electrodes to monitor your brain activity, ferromagnetic implants in your ears or eyes, bullet fragments, other metal devices or objects implanted in the head.
9. TMS Therapy is not effective for all patients with depression. Any signs or symptoms of worsening depression should be reported to the doctor and/or staff member.

10. Although extremely rare, seizures have been reported during the use of TMS devices. The estimated risk of seizure is approximately 1/30,000 treatments or 1 in 1000 patients (0.1% of patients).

11. Because the TMS Therapy system produces a repetitive clicking sound, I understand that I should wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment.

12. 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.

13. I understand that I may discontinue TMS treatment at any time.

14. My physician has also explained the risks/benefits of other treatment options such as ECT.

I have read the information contained in this Medical Procedure Consent Form about TMS Therapy and its potential risks, I have discussed it with the doctor who has answered all my questions. I understand there are other treatment options for my depression available to me and this has also been discussed with me. I therefore permit the doctor and staff members to administer this treatment to me.

Patient/Legal Representative Name _____

Date _____ **Patient/Legal Representative Signature** _____

Physician Name _____

Date _____ **Physician Signature** _____

License No. _____

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