

Patient Consent for TMS Therapy

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

Dr. Ganapathy has explained the following information to me:

1. TMS stands for “Transcranial Magnetic Stimulation”. TMS Therapy is a medical procedure. A TMS treatment session is conducted using a device called the MagVenture TMS Therapy System. This system provides electrical energy to a “treatment coil” or magnet that delivers a pulsed magnetic field. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.
2. TMS Therapy is a safe and effective treatment for those patients with depression who have not benefited from medication given at high enough dose and for a long enough period of time but did not improve.
3. During a TMS treatment session, Dr. Ganapathy or a member of the TMS Therapeutics staff will place a magnetic coil gently against the patient's scalp on the left front region of the patient's head.
4. To administer the treatment, Dr. Ganapathy or a member of TMS staff, will first position my head in the head support system. Next, the magnetic coil will be placed on the left side of my head, and I will hear a clicking sound and feel a tapping sensation on my scalp. The doctor will then adjust the TMS System so that the device will give just enough energy to send electromagnetic pulses into the brain so that my right hand moves slightly in a twitching motion. The amount of energy required to make my hand twitch is called the “motor threshold”. Treatments are given at an energy level that is just above my individual motor threshold. How often my motor threshold is re-evaluated will be determined by Dr. Ganapathy.
5. Once a motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment for depression as a series of “pulses” that last about 2 seconds, with a “rest” period of about 8 seconds between each series. Treatment is to the left of the front side of my head and will take about 3 minutes. Also, I will receive the anxiety treatment as a series of “pulses” that last about 10 seconds, with a “rest” period of about 1 second between each series. Treatment is to the right of the front side of my head and will take about 15-30 minutes. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. I will likely receive these treatments 5 times a week for 6 weeks (30

treatments). I will be evaluated by Dr. Ganapathy periodically during this treatment course. The treatment is designed to reduce my current symptoms of my illness.

6. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations were reported by about one third of the patients who participated in the research studies. I understand that I should inform Dr. Ganapathy or a member of the Envision Mind Care staff if this occurs. The doctor may then adjust the dose or make changes to the where the coil is placed in order to help make the procedure more comfortable for me. I also understand that headaches were reported in a significant number of patients who participated in the clinical trials. I understand that both discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications such as acetaminophen if a headache occurs.
7. The following risks are also involved with this treatment: The MagVenture TMS Therapy System should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the TMS magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. An object that may have this kind of metal includes: a.) Aneurysm clips or coils b.) Stents c.) Implanted Stimulators d.) Electrodes to monitor your brain activity e.) Ferromagnetic implants in your ears or eyes f.) Bullet fragments.
8. TMS 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.
9. Seizures have been reported to occur rarely with TMS. The current estimated risk of seizure is 1 in 30,000 treatments (0.003%) to 1 in 1,000 patients (0.1%).
10. Because the TMS Therapy system produces a loud click with each magnetic pulse, I understand that I must wear earplugs or similar hearing protection devices with a rating of 30 dB or higher of noise reduction during treatment.
11. 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.
12. 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 risks. I have discussed it with Dr. Ganapathy who has answered all of 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 Dr. Ganapathy or a member of the Envision Mind Care staff to administer this treatment to me.

I understand the novel Coronavirus causes the disease known as COVID-19. I understand the novel coronavirus has a long incubation period during which carriers of the virus may not show symptoms and still be contagious.

I understand that due to the frequency visits of other patients, the characteristics of the novel coronavirus, and the characteristics of rTMS procedures, that I have an elevated risk of contracting the novel coronavirus simply by being in a medical office.

I knowingly and willingly consent to have the rTMS treatment completed during the COVID-19 pandemic.

Patient / Representative

Print Name :

Date :

Signature :

Witness

Print Name :

Date :

Signature :