

TMS SERVICES

2820 Village Parkway, Suite 620 Highland Village, TX 75077

Patient Consent for a Medical Procedure

Apollo TMS Therapy

Patient Name _____

Date _____

The Costello Clinic has partnered with Neurocare Group and is now rebranding as Dallas Neurocare Therapy.

This is a patient consent for a medical procedure called Apollo 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 Apollo TMS Therapy.

The information contained in this consent form is also described in the Depression Patient's Manual for Transcranial Magnetic Stimulation with the Apollo TMS Therapy® System which is available from your doctor. Not all information in the Manual is stated here, so you should read the Patient Manual and discuss any questions that you have with your doctor. Once you have reviewed the manual and this consent form, be sure to ask your doctor any questions that you may have about Apollo TMS Therapy.

Dr. Costello has explained the following information to me:

- a. TMS stands for "Transcranial Magnetic Stimulation" Apollo TMS Therapy® is a medical procedure. A TMS treatment session is conducted using a device called the Apollo TMS Therapy System, 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. Apollo TMS Therapy® is a safe and effective treatment for patient with depression who have not benefitted from antidepressant medications.
- c. Specifically, Apollo TMS Therapy has been shown to relieve depression symptoms in adult patients who have been treated with one antidepressant medication given at a high enough dose and for a long enough period of time but did not experience improvement.
- d. At this time, there are no studies that show Apollo TMS therapy works for patients who did not experience improvement after taking two or more antidepressant medications at a high enough dose and for a long enough period of time or who did not take any antidepressants during this current period of depression.
- e. During a TMS treatment session, the doctor or a member of their staff will place the magnetic coil gently against my scalp on the left front region of my head. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists think may be responsible for causing depression.

PT Initials: _____

Clinician Initials: _____

- f. To administer the treatment, the doctor or a certified member of their 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 Apollo TMS Therapy system so that the device will give just enough energy to send electromagnetic pulses into the brain so that my right hand will twitch. 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 frequently my motor threshold will be re-evaluated will be determined by my doctor.
- g. Once motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of “pulses” that last about four seconds, with a “rest” period of about 26 seconds between each series. Treatment is to the left front side of my head and will take about 40 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 be evaluated by a doctor or nurse practitioner several times during this treatment course. The treatment is designed to relieve my current symptoms of depression.
- h. 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 the doctor or his/her staff if this occurs. The doctor may then adjust the dose or make changes to where the coil is placed in order to help make the procedure more comfortable for me. I also understand that headaches were reported in half of the patients who participated in the clinical trial for the Apollo device. 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.
- i. The following risks are also involved with this treatment:

The Apollo TMS system should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the Apollo magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. Objects that may have this kind of metal includes:

- Aneurysm clips or coils
- Stents
- Implanted Stimulators
- Electrodes to monitor your brain activity

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