



Patient Information & Consent for TMS Therapy

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, and the potential benefits of this treatment.

TMS Therapy Introduction:

The following information has been explained to me:

TMS stands for "Transcranial Magnetic Stimulation" and 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 directed magnetic fields. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.

TMS Therapy is a safe and generally effective treatment for patients with depression who have not benefitted from antidepressant medications. Specifically, 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 get better.

Description of the Procedure/Treatment Protocol:

During a TMS treatment session, a team member will place the magnetic coil gently against your scalp on the left front region of your 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.

To set the prescription for the treatment, your doctor, or a member of his/her staff, will first position a treatment cap on your head. Next, the magnetic coil will be placed on your head, and you will hear a clicking sound and feel a tapping sensation on your scalp.

Once motor threshold is determined, the magnetic coil will be moved, and you will receive the treatment by a team member as a series of "pulses" that last about 4 seconds each, with a "rest" period of between 10-20 seconds intervals between each series. Treatment will generally take anywhere from 20-50 minutes, depending what protocols, intensity and number of treatment sites your doctor has prescribed. This treatment does not involve any anesthesia or sedation and you will remain awake and alert during the treatment. You will likely receive these treatments 5 times a week for 6 to 7 weeks (30 to 36 treatments). You will be evaluated by a doctor as needed during this treatment course.

Risks/Side Effects:

During the treatment, you may experience tapping or uncomfortable 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 clinical studies used for FDA approval. You should inform the doctor or his/her 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. Headaches were also reported in half of the patients who participated in the clinical trial for FDA approval of the device. Generally, both discomfort and headaches got better over time in the research studies. You may take common over-the-counter pain medications such as acetaminophen if a headache occurs. Rarely, fatigue, or nausea can occur as well.

The following risks are also involved with this treatment:

The TMS Therapy System should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death.

The TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators (ICDs) or are using wearable cardioverter defibrillators (WCD). Failure to follow this restriction could result in serious injury or death.

You also agree to remove any of the following out of the range of 30 cm (typically neckline and up) during the treatment, as such items may interfere with treatment or be damaged.

- Cardiac Pacemakers, ICDs
- Vagus Nerve Stimulators
- Wearable Cardioverter Defibrillator
- Wearable Infusion Pump
- Magnetically programmable shunt valves
- Wristwatches, smartwatches
- Metal Framed Eyeglasses
- Hearing Aids
- Cell Phones, PDAs
- Tablets
- Portable MP3 Players
- Removable Dentures/ Bridgework
- Any Jewelry and Hair Barrettes

Temporary emotional highs and lows are common during the first weeks of treatment and are to be expected. 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. TMS Therapy is not effective for all patients with depression.

Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. However, since the introduction of the TMS System into clinical practice, seizures have been rarely reported.

Because the TMS Therapy system produces a loud click with each magnetic pulse you must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment.

Results:

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. You will work with your doctor to set a treatment course in an effort to achieve reduction or remission of your symptoms.

Right to Refuse or Withdraw:

You have the right to refuse treatment or discontinue treatment at any time.

CONSENT:

I have read the information contained herein about TMS Therapy. I have had the opportunity to discuss it with my doctor who has answered all of my questions. I understand there are other available treatment options, which have been discussed. I hereby consent to receiving TMS Therapy.

Patient / Guardian Signature

Date

Witness Signature

Date



Precautionary Coronavirus Liability Release Form

Due to the 2019-2020 outbreak of Coronavirus, COVID-19, we are taking extra precautions with the intake of each client, health history review, as well as sanitation and disinfecting practices. Please complete the following and sign below.

Symptoms of COVID-19 include:

- Fever
- Fatigue
- Dry cough
- Difficulty breathing

I, _____ agree to the following: I understand the above symptoms and affirm that I, as well as all household members, do not currently have, nor have experienced the symptoms listed above within the last 14 days.

I affirm that I, as well as all household members, have not been diagnosed with COVID19 within the last 30 days. I affirm that I, as well as all household members, have not knowingly been exposed to anyone diagnosed with COVID-19 within the last 30 days.

I affirm that I, as well as all household members, have not traveled outside of the country, or to any city outside of our own that is or has been considered a "hot spot" for COVID-19 infections within the last 30 days.

I understand that Acuity TMS of Plano, and its associates cannot be held liable for any exposure to the virus or any other contagion caused by misinformation on this form or the health history provided by each client.

By signing below, I agree to each above statement and release Acuity TMS of Plano, and its associates from any and all liability for the unintentional exposure or harm due to COVID-19.

All employees of this practice agree that they abide by these same standards and affirm the same. We also affirm that we have improved and expanded our sanitation protocols to more thoroughly fight the spread of COVID-19 and other communicable conditions.

Signature _____ Date _____