



Vital TMS Therapy  
5550 Friendship Blvd, Suite 595  
Chevy Chase, MD 20815  
202-335-4114

## PATIENT CONSENT FOR A MEDICAL PROCEDURE

This is a patient consent for a medical procedure called Transcranial Magnetic Stimulation(TMS) and/or Theta Burst Stimulation(TBS). 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 or TBS. Once you have reviewed the manual and this consent form, be sure to ask your doctor any questions that you may have about TMS Therapy.

Dr. Anca Zinnes or Dr. Alvaro Guzman and/or the Vital TMS Therapy staff have explained the following information to me:

- a. TMS stands for “Transcranial Magnetic Stimulation” and it is a medical procedure. A TMS treatment session is conducted using a device called the Cloud 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 1.5 tesla but the energy is much more focused in TMS to allow for the stimulation of neurons 2 cm deep into the brain. 1.5 tesla in enough electromagnetic energy to lift a car so this is not a TENS Unit for sure.
- b. TMS therapy is FDA approved for treatment resistant depression since 2008 for those who have not responded to medications. It is also reported to be safe and effective treatment for patients with some pain syndromes, anxiety, BiPolar Disorders, ADHD, TBI, poststroke, autism, brain enhancement ect...but then it is considered off label.
- c. TMS Therapy has been shown to relieve depression symptoms in adult patients who have been treated with prior antidepressant medications but did not get better.
- d. During a TMS treatment session, the doctor or a member of the certified Vital TMS Therapy 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 a

the region of the brain that scientists think may be responsible for causing or adding to the severity of my illness ie the prefrontal cortex.

- e. For the mapping procedure which happens the very first session the doctor or a member of the staff will first position my head as I sit in the treatment chair. 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 Therapy system so that the device will give just enough energy to send electromagnetic pulses into the 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. My doctor will determine how often my motor threshold will be re-evaluated.
  
- f. The following visit is when the treatment actually begins. When the motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of “pulses”. Treatment is to the left or R front side of my head and will take about 20 minutes. I understand that this treatment does not involve an 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). A taper of 3-2-1 for a total of 36 treatments will follow this. The doctor will regularly evaluate me during this treatment course. The treatment is designed to provide relief from my presenting symptoms.
  
- g. An Alternative process is called TBS but it is not yet FDA approved so it will not be covered by insurance. Using a different wavelength of three pulses at 50 Hz(so extremely tight with just milliseconds between them) at a rate of 5Hz(4 to 8 Hz is the Theta) for 2 seconds, as opposed to the 10Hz used in rTMS, the coil is similarly placed on the left side of the patient’s head for about 10 minutes or the right side for about 39 seconds.
  
- h. We have had excellent results using the coil directly on the body but this is not FDA approved and off label so insurance will not cover this treatment.
  
- i. The following risks are possible with both techniques:

TMS should not be used by anyone who has magnetic-sensitive metal in their head or has magnetic-sensitive metal within 12 inches of the treatment 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
  - 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
- j. TMS 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.
- k. TMS is not effective for all patients. Any signs or symptoms of worsening of presenting symptoms 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 symptoms.
- l. Although the risk of seizures(sometimes called convulsions or fits)is low, some 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 in 1 in 1,000 patients. This is less than the incidence with the use of psychotropic medications.
- m. Because the TMS system produces a loud click I understand I must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during the treatment.
- n. The TMS system is an FDA approved treatment. The TBS system is considered an off-label use as the application for FDA approval is pending.
- o. I understand that most patients who benefit from TMS experience results by the fourth week of treatment; the TBS reports benefit in 2 weeks. Some patients may experience results in less time while others may take longer.
- p. I understand that I may discontinue treatment at any time.
- q. Alternative treatment for the above illness would be Ketamine IV Infusions as well as Electro Convulsive Shock Treatments (ECT) or more medications and CBT.

I have read the information contained in this Medical Procedure Consent Form about TMS and its potential risks. I have discussed it with my doctor and/or the staff at Vital

TMS Therapy 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. Anca Zinnes or Alvero Guzman and The Vital TMS Therapy staff to administer this treatment to me.

Disclosure: The Cloud TMS System is currently owned by Vital TMS Therapy

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***Patient***

***Witness***

***Date***



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## PATIENT THETA BURST CONSENT FORM

This is a patient consent form for a medical procedure called Theta Burst that covered by most insurance companies. The procedure is FDA approved for treatment resistant depression with sessions lasting 3 minutes given five days a week for a total of 36 sessions that are considered to be equivalent to traditional TMS.

In the Theta Burst protocol we use at Vital TMS Therapy, the sessions are stacked back to back in hopes of a faster result. So rather than lasting 3 minutes they might last anywhere from 9 minutes to 18 minutes depending on the situation.

This method helps patients with a wide variety of mental health disorders, and has been effective for both adults and children as young as six. Some studies have used TMS on children much younger with no complications reported. The results have been often very dramatic but not everyone responds. We are not aware of anybody having serious detrimental effects after this procedure.

We estimate achieving a solid 70% response rate and around 50% remission rates when it comes to depression but our sample is relatively small. This procedure may not be suitable for everyone so we encourage you to ask questions and do your own due diligence and research. We do not claim this to be a cure for any condition.

Theta Burst is a development that borrows from Transcranial Magnetic Stimulation or TMS which was approved by the FDA in 2008 for treatment resistant depression. This is considered to be a very effective and safe treatment that is growing in its applications. A TMS treatment session is conducted using a coil or magnet that delivers a pulsed magnetic field at a variety of frequencies. This is very similar to what a Magnetic Resonance Imaging device (MRI) does except that with TMS the energy is much more focused and allows for the stimulations of neurons up to 2 cm deep into the brain. Both systems are generally rated at 1.5 Tesla. In theory 1 Tesla is enough energy to lift a car so these are quite powerful machines but work differently.

Theta Burst uses the same machine that is used for conventional TMS but we use different settings on the equipment stimulating the neurons in the brain and causing increases in blood flow, oxygenation, BDNF, calcium channels, stem cell activation, ect. During a Theta Burst

session, the doctor or a member of the certified staff will place the coil over different parts of the head to either stimulate or inhibit different circuits in the brain. The magnetic field then will be adjusted gradually to a comfortable level and should not cause any pain.

The sessions will take about 15 minutes. We recommend at least 36 sessions and in certain situations more may be needed.

The procedure is not recommended for a person that has any kind of ferrous metal in the head as coming too close with the magnetic pulse might cause the metal to heat up or be displaced causing tissue injury. Remember however that the energy quickly dissipates after penetrating just 2 cm so the risk is very low as long as we know what to stay away from.

All TMS treatments carry a warning for seizures through it is a very rare occurrence. In fact, TMS therapy is actually being investigated to treat seizures.

The machine produces a tapping sound similar to a (MRI) during the sessions. Since it can be loud the manufacturer of the system recommends that ear plugs be worn. If you opt not to wear them against medical advice we ask that you initial here \_\_\_\_\_.

Alternatives to Theta Burst might involve traditional TMS, ECT, Ketamine, Therapy, CBT, Medications, ect...

I have read the above information concerning non FDA approved Theta Burst and Doctor Anca Zinnes or Dr. Alvaro Guzman and/or the Vital TMS Therapy staff has answered all my questions. I understand that there is no guarantee of success and fees are non-refundable. I also understand I can discontinue from the protocol at any time.

\_\_\_\_\_  
*Patient Name*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date*





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TMS 15 MINUTES LATE/NO CALL NO SHOW POLICY

TMS appointments are designated a 30 minute window within our daily schedule. Because of our very busy and compact schedule, it is important that our patients arrive on time. Patients who arrive 15 minutes AFTER their appointment time will not be seen. The appointment will be canceled and will resume the next business day. If you are unable to make your appointment time please call at least one hour prior to your scheduled appointment. NO CALL NO SHOW'S will result in a \$25 fee.

(Please initial) \_\_\_\_\_ I have read and understand the 15 minutes late/no call no show policy.

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Date:*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date:*



