TMS

PATIENT CONSENT FOR TREATMENT
FINANCIAL RESPONSIBILITY | OFFICE POLICIES

This consent form outlines the treatment that your doctor has prescribed for you; Transcranial Magnetic Stimulation (TMS), the potential risks of this treatment, the potential benefits of this treatment to you, and any alternative treatments that are available if you decide not to be treated with TMS.

The information contained in this consent form is also described in the Manufacturers' information. Once you have reviewed this consent form, be sure to ask your doctor any questions that you may have about TMS and its use in treating depression.

Dr._____ has explained the following information to me:

1. TMS stands for **"Transcranial Magnetic Stimulation"** and can be used as a medical procedure. A TMS treatment session is conducted using a device called a magnetic stimulator which provides electrical energy to a treatment coil that delivers pulsed magnetic fields. These magnetic fields are the same strength as those used in magnetic resonance imaging (MRI) machines.
2. TMS instruments are a safe and effective treatment for patients with depression who have not benefitted from antidepressant medications.
3. TMS has been shown to relieve depression symptoms in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
4. During a TMS treatment session, the doctor or a member of their staff will place a coil gently against my scalp on the left front region of my head. The doctor will then adjust the instrument 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 motor threshold. My doctor will determine how often my motor threshold will be re-evaluated.
5. Once the motor threshold is determined, a coil will be placed on a different region of my head. I will then receive the treatment as a series of "pulses" that last 4 seconds, with a rest period of 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 receive these treatments 5 times a week for 6 weeks (30 treatments). I will be evaluated by my physician during this treatment course.

6. During the treatment, I may experience tapping or mild discomfort at the treatment site while the treatment coil is in operation. 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 to help make the procedure more comfortable for me. I also understand that headaches are commonly reported and that both discomfort and headaches get better over time in the research studies and that I may take pain medication as directed by my physician.

TMS Therapy is contraindicated for use on some patients, as identified in the sections below.

In these circumstances, the prescribing clinician must exercise their clinical judgment to determine if the benefit of the treatment outweighs the possible risk to the patient. If there is any doubt you should not be treated. The possible risks and potential benefits should be clearly explained to you before treatment.

- Patients, where the skin in the area to be contacted, is broken
- Pregnant women
- Patients with
- Epilepsy or a history of seizures.
- A family history of seizures.
- Brain lesions that could affect seizure threshold.
- Tricyclic antidepressants, neuroleptic agents or any other drug that could lower the seizure threshold.
- Sleep deprivation.
- Heavy consumption of alcohol or those using epileptogenic drugs.
- Severe heart disease.
- Increased intracranial pressure.
- Uncontrolled migraines.
- Implanted Electronic Devices and/or Conductive Objects:

HORIZON™ treatment coils produce very strong pulsed magnetic fields that can affect certain implanted devices or objects. The magnetic field strength diminishes quickly with increasing distance from the coil. At ~30 cm from the face of the treatment coil, the peak magnetic field is sufficiently diminished to allow for the safe use of many electronic devices, however, this may vary between implanted devices and should be investigated before treatment.

- **Metallic Objects in or near the Head:**

HORIZON™ is contraindicated for use on patients having conductive, ferromagnetic, or other magnetic-sensitive metals in the head or within 30cm of the treatment coil; this includes stimulator devices implanted in or near the head e.g. active or inactive implants (including device leads), including deep brain stimulators, cochlear implants, and vagus nerve stimulators.

- **Implants Controlled by Physiological Signals:**

HORIZON™ is contraindicated for use on patients who have an implanted device that is activated or controlled in any way by physiologic signals, even if the device is located outside the 30cm distance. This includes pacemakers, implantable cardioverter defibrillators (ICD's) and vagus nerve stimulators (VNS). The device is also contraindicated for patients using wearable cardioverter defibrillators (WCD), even if the device is removed, due to the potentially unstable cardiac condition of such patients.

- **Implants Not Controlled by Physiological Signals:**

Patients may have other implanted devices or metallic objects located in areas outside the 30cm distance from the coil during TMS Therapy if such devices are not controlled by physiologic signals. Examples include sutures and implanted insulin pumps.

However, great care must be taken by the operator to ensure that the treatment coil is never placed within 30cm of these implants, otherwise serious injury could result.

- **Wearable or Removable Devices:**

If patients have removable devices or objects that may be affected by the magnetic field, the device(s) should be removed from the patient area before treatment (e.g. earrings, hearing aids, eyeglasses, cell phones, MP3 players, etc.) to prevent possible injury or damage to the device. This also includes wearable monitors and bone growth stimulators.

Transcranial magnetic stimulation 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. Seizures have been reported with the use of TMS devices. The estimated risk of seizure when using the clinically cleared (FDA) procedure is approximately 1 in 30,000 treatments.

During the TMS treatment protocol, the stimulator system generates a click with each magnetic pulse. I understand that the use of earplugs or other hearing protection devices is required. The Manufacturer mandates hearing protection with a rating of 30dB or higher noise reduction during treatment.

I _____, have read the information about transcranial magnetic stimulation (TMS) therapy contained in this Medical Procedure Consent Form and the potential risks.

I have discussed the treatment with Dr_____, who has answered all my questions and clearly explained the risks and benefits to me. I understand there are other treatment options available for my depression and this has also been discussed with me.

TMS FINANCIAL RESPONSIBILITY | OFFICE POLICIES

Appointment/Cancellations

____ We have reserved a special time just for you so that you can have the time that you deserve with your Provider without being rushed. To ensure that each patient is given the proper amount of time allotted for their visit and to provide the highest quality care. Arriving late to your appointment will have negative implications as late appointments will be considered as **"same day cancellation"**. You may have to re-schedule your appointment. Please be on time.

____ When you do not show up for a scheduled appointment, you are taking an appointment slot that could have been used for another patient. Again, we understand that emergencies happen and we can assure you that we will work with these circumstances when they arise on a case-by-case basis.

____ To have an efficient and orderly practice, we request your consideration of the physician's time by asking that you call the office **forty-eight hours (48 hours')** in advance if you need to cancel, change, or reschedule an appointment. This will give our staff plenty of time to notify those patients that are in our "waiting list" for any cancellations.

Dismissal

____In the event a patient has incurred three (3) documented "no-shows" and/or "same-day cancellations," the patient may be subject to dismissal from MindHope.

____ If you are **NOT COMPLIANT** with your treatment recommendations, do not keep up with your scheduled appointments, do not comply with your financial responsibility(***when applicable***) , if your conduct in the office or with the staff is disruptive or inappropriate **YOU WILL BE DISCHARGE** from the practice under these circumstances.

Other Information/Service Charges

___ **TMS Psychiatric Evaluations** are between 1-2 hours long. This evaluation is to establish not only rapport between you and the Provider but also to establish your Mental Health Treatment Plan accordingly to the Provider recommendations.

____ For the preparation and completion of letters, certificates, reports, and forms there will be a charge depending on the document requested in addition to an administrative fee of **$5.00** All photocopies of medical records will be charged **$1.00** per page in addition to the administrative fee. For pricing of document preparation please contact our office to speak with one of our professional team members.

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FINANCIAL RESPONSIBILITY

____ If plan to use your credit card to make a payment please make sure that it is in good standing. You understand that If you close your credit card account or wish to use a different credit card it is your responsibility to notify the MindHope team immediately.

____ Failure to comply with our **CANCELLATION** policy will result in a charge bill to you for the amount of **$150** for the scheduled **TMS** follow up appointment.

____ If your missed appointment is for **"subsequent motor threshold re-determination and management"** the amount billed to you will be for **$190. Please be advised that this is a very important appointment as the Psychiatrist is scheduled to do a re-evaluation and determination of your TMS treatment. This is the time for the Psychiatrist to evaluate your TMS treatment progress.**

_____ Your insurance carrier will **NOT** reimburse the physician for your missed appointment ***therefore it is your responsibility to pay the full amount of any missed appointment before your next appointment.***

____ I will notify the MindHope team in writing within **7 business days** in advance if I decide to discontinue treatment.

TMS requires a tremendous commitment from your part as you would set aside between **5-6 weeks** from **Monday through Friday** to receive this treatment. If you are doing this is because you have done your research and have come to the conclusion that this is the best course of action for you. This information is provided for your convenience so that you will be aware of your financial responsibility for your medical care, which you have or will receive and to be aware of our office policies.

Our goal is that you have the best experience but we can only do this if you help us in this process

Print Name:_____ Patient Signature:_____ Date:_____

We understand that emergencies happen and we can assure you that we will work with these circumstances when they arise on a case-by-case basis.

I therefore authorize Dr. _____ and his/her trained staff to administer TMS therapy to me and agree that this is the best treatment option for me.

Patient Signature: _____ Date: _____ Time: _____

Patient Print Name: _____

Witness Signature _____ Date: _____ Time: _____

Physician Print Name _____

Physician Signature _____ Date: _____ Time: _____