Transcranial Magnetic Stimulation (TMS) Information Packet

What is TMS?

Transcranial Magnetic Stimulation (TMS) is a non-invasive, safe, and painless medical procedure utilizing a brain stimulation technique used to treat individuals with certain psychiatric conditions. It is FDA cleared for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD).

When is TMS used?

The U.S. Food & Drug Administration (FDA) has approved treatment with TMS for patients with MDD and OCD who have not responded to conventional antidepressant medication treatment.

Antidepressant medication and psychotherapy are the first line treatments for patients with MDD and OCD. These treatments, however, do not work for all patients. In these instances, TMS might be used as an alternative treatment, or to augment antidepressant medication or psychotherapy.

How does TMS work?

TMS uses magnetic fields to stimulate nerve cells in the brain using an electromagnet that is placed over your scalp. The magnetic field is the same type and strength as those used in magnetic resonance imaging (MRI) machines. The electromagnet painlessly delivers a brief electromagnetic pulse that stimulates nerve cells in specific areas of your brain to relieve depression or other symptoms for which it is being used.



In depressed patients, electrical activity in certain areas of the brain decreases. (Illustrative images based on PET scans)

Benefits

TMS has been demonstrated to be a safe and well-tolerated procedure that can be an effective treatment for adults with MDD or OCD who have not benefitted from antidepressant medications or psychotherapy. The primary potential benefit of TMS is that it may lead to improvements in the symptoms of depression or other medical conditions. However, not all patients respond equally to TMS. Like all forms of medical treatment, some patients recover quickly, others recover briefly and experience a relapse, while others may have no response to therapy at all.

Alternatives to TMS

There are alternative treatments available including pharmacotherapy, cognitive behavioral therapy (CBT), psychotherapy, and electroconvulsive therapy (ECT).

Pharmacotherapy options include selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants (TCAs), and second-generation antipsychotics (SGAs).

During each TMS session, it is important to remove any metal or magnetic sensitive objects (i.e., jewelry, keys, credit cards). Patients are required to wear earplugs during treatment for their comfort and hearing protection, as the TMS machine produces loud clicking sounds with each pulse, much like an MRI machine. TMS does not require any anesthesia or sedation, so patients are awake and alert during the entire procedure.

TMS Protocol for Patients with Major Depressive Disorder (MDD)

TMS therapy involves a series of thirty-six treatments for patients with major depressive disorder (MDD). Generally, sessions are conducted daily, five times a week, for six weeks followed by a three-week taper period.

Brain Mapping + First Treatment

The first step for successful TMS treatment is effective mapping of the patient's brain to determine which point on the head should receive stimulation. During the mapping session, the technician will use the TMS device to send magnetic pulses and register the brain's response until the optimal point is identified. This visit will take approximately 45 minutes and includes both the mapping process and the first TMS treatment.

6-Week Treatment Course

Patients come in for treatment five days per week (Monday-Friday) for six weeks. After mapping, subsequent treatment sessions last approximately 20 minutes. Patients are asked to complete a weekly evaluation to measure progress. If determined necessary at any point during treatment, the technician may perform a remapping to improve treatment effectiveness.

3-Week Taper Period

After the six-week treatment course, there is a three-week taper period. Patients will need to come into the office for three TMS sessions in the seventh week, two sessions in the eighth week, and one final session in the ninth week.

TMS Protocol for Patients with Obsessive-Compulsive Disorder (OCD)

TMS therapy involves a series of twenty-nine treatments for patients with obsessive-compulsive disorder (OCD). Generally, sessions are carried out daily, five times a week, for five weeks followed by a two-week taper period. Prior to each treatment, patients undergo individually tailored provocations to activate the abnormal OCD circuitry (for instance, asking a person with germ-related obsessions and compulsions to touch the floor and then not use hand sanitizer).

Brain Mapping + First Treatment

The first step for successful TMS treatment is effective mapping of the patient's brain to determine which point on the head should receive stimulation. During the mapping session, the technician will use the TMS device to send magnetic pulses and register the brain's response until the optimal point is identified. This visit will take approximately 45 minutes and includes both the mapping process and the first TMS treatment.

5-Week Treatment Course

Patients come in for treatment five days per week (Monday-Friday) for five weeks. After mapping, subsequent treatment sessions last approximately 20 minutes. Patients are asked to complete a weekly evaluation to measure progress. If determined necessary at any point during treatment, the technician may perform a remapping to improve treatment effectiveness.

2-Week Taper Period

After the five-week treatment course, there is a two-week taper period. Patients will need to come into the office for two TMS sessions in the seventh week and two final sessions in the eighth week.

Noting Progress

Patients may begin to experience results in the first two weeks of treatment and report an increase in energy, desire, motivation, and improved sleep. However, some patients report an improvement in their mood but find their symptoms begin to return, what we refer to as "dips." Dips in mood are common and does not mean that TMS is not working, rather, it is an indication of the need for more treatments to stabilize mood.

Patients will be asked to complete a questionnaire after every fifth treatment to measure treatment progress.

Patients receiving treatment with TMS for MDD will complete the Patient Health Questionnaire (PHQ-9).

- The PHQ-9 is a 9-item ordinal scale (0-3) which scores each of the 9 DSM-V criteria as "0" (not at all) to "3" (nearly every day). The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression.

Patients receiving treatment with TMS for <u>OCD</u> will complete a <u>Yale Brown Obsessive-Compulsive Scale (Y-BOCS)</u>.

- The Y-BOCS is a 10-item ordinal scale (0–4) that rates the severity separately for both obsessions and compulsions of OCD according to the time occupied, degree of interference, subjective distress, internal resistance, and degree of control.

Who Should Not Receive Treatment with TMS?

Patients should not receive treatment with TMS if they have: a history of seizures or a seizure disorder, presence of acute or chronic psychotic symptoms or disorders, neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system, or excessive use of alcohol or illicit substances within the last 30 days.

Patients with any type of non-removable metal in their heads (except for braces or dental fillings), should not receive TMS. Failure to follow this rule could cause the object to heat up, move, or malfunction, and result in severe injury or death. The following is a list of metal implants that can prevent a patient from receiving TMS:

- Aneurysm clips or coils
- Stents in the neck or brain
- Deep brain stimulators
- Electrodes to monitor brain activity
- Cochlear implants in your ears.

- Shrapnel or bullet fragments in or near the head
- Facial tattoos with metallic or magneticsensitive ink. If someone had an MRI done in past, they can do TMS.

Risks and Adverse Effects

As with any medical treatment, TMS carries a risk of side effects. However, TMS is well tolerated and only a small percentage of patients discontinue treatment because of side effects.

Up to 10% of patients undergoing TMS experience headaches, application site pain or discomfort, jaw pain, facial pain, muscle pain, spasm or twitching, and neck pain were reported as either mild or moderate and resolved shortly after treatment. You can take ibuprofen, acetaminophen, or aspirin, which in most cases relieves the pain.

TMS produces a loud clicking noise during stimulation, which can result in tinnitus or hearing loss especially if ear protection is not used. To prevent risk of hearing disturbances, earplugs will be given to wear. The risk for hearing loss with hearing protection is not known but is less than 0.01% or 1 in 10,000 patients.

TMS can induce a convulsion even in the absence of brain lesions, epilepsy, or other risk factors for seizures. The overall risk for seizures during TMS is not known but it is less frequent than 0.5% or 5 in 1,000 patients. TMS does not cause epilepsy. In patients with known epilepsy, the risk is 1%.

TMS could theoretically induce transient changes in cognition or movement, although safety studies have not found such side effects to date.

Pregnancy

Since TMS therapy is a relatively new medical procedure, there is little current evidence available for the safety of TMS therapy during pregnancy. However, there have been small studies that have followed women receiving TMS therapy during their pregnancies and after birth.

In these studies, no complications to the pregnancy or the child were observed. Furthermore, TMS is not a systemic treatment, with the energy during the TMS therapy session delivered in a small area of the brain with no direct energy anatomically near the developing child.

Long Term Adverse Effects

There are no known long-term adverse effects reported with the use of TMS therapy. However, as this is a relatively new treatment, there may be unforeseen risks in the long-term that are currently unknown.

Insurance Coverage

Although it is an FDA-approved treatment, insurance providers require a pre-authorization to determine medical necessity. Coverage criteria varies between insurance providers and your specific plan's policy, and we cannot guarantee how insurance will decide your case. We typically receive a response from insurance within one to two weeks after submitting the required paperwork for the pre-authorization.

The TMS Better Living team will gladly conduct a benefits investigation on your behalf and can provide information such as general plan benefits, deductible amounts, and general TMS Therapy coverage information. We will also provide you with the necessary information for you to reach out to your insurance company and argue on your own behalf for coverage.

<u>If you have not done so already, please have your referring or previous provider fax copies of your medical record to our office at (214) 613-1667 to help expedite the insurance pre-authorization.</u>

Indications for Coverage

Adults 18 years and older with a confirmed diagnosis of either:

- A) Moderate to Severe Major Depressive Disorder (MDD), either single episode or recurrent or B) Obsessive-Compulsive Disorder (OCD).
- B) AND one or more of the following:
- Patient has tried and had an inadequate response to 2 antidepressant agents from 2 different antidepressant classes (i.e., selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, tricyclic antidepressants, bupropion, or mirtazapine).
- Patient has failed a trial of a psychotherapy known to be effective in the treatment of major depressive disorder and obsessive-compulsive disorder (i.e., cognitive behavioral therapy) of an adequate frequency and duration, without significant improvement in depressive or OCD symptoms.

Cancellation Policy

The success of this treatment is dependent upon the continuity of your TMS sessions. We understand that it is difficult to commit to daily and weekly treatments, which is why we schedule TMS sessions in advance.

We will always do our best to accommodate the scheduling changes that you may have, but there will be instances where we are not always able to accommodate these changes.

If we do not receive a request to change the appointment time 24 hours prior to the appointment, we may not be able to provide treatment that day. If we are unable to reschedule your session, you may be responsible for full payment of the missed TMS appointment.

Further Questions

Please write down any questions you may have regarding treatment with TMS.