

Adverse Events

Table 1 below presents the adverse events reported in the clinical study in 5% or more of the patients who received the **BrainsWay** DTMS treatment or the sham (placebo) treatment. Safety information is provided from all patients who were treated in the clinical study.

Table 1 - Adverse Events

Anticipated Event	Deep TMS Treatment (N=48 Subjects)		Sham Treatment (N=51 Subjects)	
	No of Subjects	Incidence	No of Subjects	Incidence
Headache	18	37.5%	18	35.29%
Anxiety	6	12.5%	2	3.92%
Pain in Jaw	4	8.33%	1	1.96%
Common cold	4	8.33%	5	9.8%
GI Symptoms	4	8.33%	0	0%
Diarrhea	3	6.25%	1	1.96%
Neck Pain	2	4.17%	3	5.88%
Fatigue	1	2.08%	5	9.8%

Headaches were reported in 37.5% of patients who received the **BrainsWay** DTMS treatment, and in 35.3% of the patients who received the sham (placebo) treatment. This indicates that headaches were not necessarily caused by the **BrainsWay** DTMS treatment. Headaches usually get better or go away altogether with successive treatments. Headaches may also be relieved by using common over-the-counter pain medications such as acetaminophen.

There were no notable differences in any of the reported adverse events in patients who received the **BrainsWay** DTMS treatment compared to patients who received the sham treatment, This indicates that these side effects were not necessarily caused by the **BrainsWay** DTMS treatment.

You should Inform the treatment administrator if you feel pain or discomfort during the treatment. The DTMS helmet may be slightly adjusted on your head to relieve the pain or discomfort. Pain and discomfort associated with treatment usually gets better or goes away altogether with successive treatments.

Other side effects which may occur but are not necessarily caused by the **BrainsWay** DTMS treatment include anxiety, pain in jaw, neck pain or fatigue.

BrainsWay Deep TMS Treatment Effectiveness Information

The safety and effectiveness of the **BrainsWay** Deep TMS system for treatment of Obsessive Compulsive Disorder was demonstrated in a prospective, double blind, randomized, controlled, multi-center trial. The study was conducted at 11 study sites in the United States (9 sites), Israel (1 site) and Canada (1 site). During the treatment phase, TMS sessions were performed daily for 6 weeks.

The primary endpoint was the change from baseline (i.e., the starting score before treatment) in a standard scale for

measuring OCD symptoms, known as the Yale-Brown Obsessive Compulsive Scale (Y-BOCS). The model estimated mean change from baseline in YBOCS scores in the Deep TMS group across 6 weeks compared to the sham group was statistically significant ($p=0.0127$). The response rate (meaning the percent of patients who had a reduction in YBOCS scores of at least 30%) was statistically significantly better in the Deep TMS group compared to the sham group. There was a statistically significant improvement in Clinical Global Impression – Improvement (CGI-I) and Clinical Global Impression – Severity (CGI-S) in patients treated with the Deep TMS treatment compared to the sham group.

The efficacy of the Deep TMS treatment was still seen at 10 weeks, based on a statistically significant change from baseline in YBOCS scores ($p=0.0380$) and a significantly better response rate in the Deep TMS group compared to the sham group ($p=0.0057$). No significant differences were found in the CGI-S and CGI-I scores at 10 weeks, however the scores were better in the Deep TMS group than in the sham group.

You may ask your doctor for more information regarding the clinical study.

Summary Information

The **BrainsWay** Deep TMS System has been shown to be safe and effective for the treatment of Obsessive Compulsive Disorder (OCD). You should discuss the treatment with your doctor to ensure that the **BrainsWay** Deep TMS treatment is the right treatment for you.

Most patients who benefit from **BrainsWay** Deep TMS experience results by the second week of treatment. Some patients may experience results in less time. The **BrainsWay** Deep TMS Treatment should be administered daily for six weeks. This is the treatment schedule that has been demonstrated as safe and effective in the clinical study.

As with any OCD treatment, there is a risk that your OCD symptoms might worsen during the **BrainsWay** Deep TMS treatment. Inform your doctor immediately if your OCD symptoms worsen.

The **BrainsWay** Deep TMS treatment has not been evaluated to be safe and effective for patients with suicidal ideation or who have recently attempted suicide.



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PATIENT MANUAL

BrainsWay Deep Transcranial Magnetic Stimulation (Deep TMS) System for Treatment of Obsessive Compulsive Disorder (OCD)

This Patient Manual is a supplement
to the BrainsWay Deep TMS System
Instructions for Use.

If you are considering **BrainsWay** Deep TMS treatment for treatment of OCD you should review this patient manual and discuss the information with your doctor in order to understand more about:

- How Deep TMS treatment works
- Who can be treated with BrainsWay Deep TMS Treatment
- Who should not be treated with BrainsWay Deep TMS Treatment
- Precautions and warnings
- Potential side effects

Introduction to BrainsWay Deep TMS Treatment

You have been diagnosed with Obsessive Compulsive Disorder (OCD) and your doctor has recommended treatment with the **BrainsWay** Deep TMS treatment to treat symptoms of OCD. **BrainsWay** Deep TMS treatment has been shown to be safe and effective in the treatment of patients with OCD.

Your Health Care Provider (psychiatrist or physician) will review your medical and OCD history to help determine if **BrainsWay** Deep TMS treatment is appropriate for you or not.

The treatment is performed under your Health Care Provider's supervision. Neither anesthesia nor sedation is required. You will be awake and alert during the treatment sessions. The treatment sessions include daily treatments for a period of 6 weeks. Each treatment session lasts approximately 20-30 minutes.

How Does BrainsWay Deep TMS Treatment Work?

DTMS stands for "Deep Transcranial Magnetic Stimulation". DTMS is a non-invasive procedure, involving stimulation of a part of the brain called the Anterior Cingulate Cortex. The stimulation activates nerve cells in this region of the brain and improves OCD symptoms.

The stimulation is produced by a treatment "coil" contained in a helmet. During treatment, the helmet is gently positioned on the frontal side of your head, over this region of the brain. Short pulses of electricity sent through the treatment coil generate magnetic fields that turn on and off very rapidly. These magnetic fields are similar to those used in magnetic resonance imaging (MRI) systems. The magnetic field goes through the head and induces a weak electrical current that briefly activates the nerve cells in this region of the brain and improves OCD symptoms.

When Should the BrainsWay Deep TMS Treatment be Used?

Patients already on OCD treatments should be maintained at their current dosages during the Deep TMS treatment.

Indications for Use

The **BrainsWay** Deep TMS System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder.

When Should the BrainsWay Deep TMS Treatment Not be Used?

DTMS treatment delivers a magnetic field that could cause any metal objects that are near the device to move or to get hot. DTMS Treatment should not be used if you have

metal implants in or around your head (except for standard amalgam dental fillings). DTMS Treatment should not be used if you have implanted electronic devices in your head. These implants could cause serious injury or death if DTMS treatment is used. You should tell your doctor if you have any metal devices or objects in your head or body in order to determine if those devices could be affected by the DTMS treatment.

BrainsWay Deep TMS Treatment Safety Information

Safety of the **BrainsWay** Deep TMS System was demonstrated in a clinical study involving 100 patients with moderate to severe Obsessive Compulsive Disorder. The patients ranged in age from 22 to 68 years.

This section summarizes the adverse events and side effects reported in the clinical study with the **BrainsWay** Deep TMS System.

- There were no deaths in patients who took part in the clinical trial.
- Systemic side effects such as weight gain, dry mouth and sexual problems were not observed.
- Tests of memory function during treatment showed no change during the clinical trial.

You should discuss the warnings and precautions related to the DTMS treatment with your doctor to determine if any precautions should be taken prior to or during your treatment with **BrainsWay** Deep TMS System.

Seizures

There were no cases of a seizure (also called convulsions) reported in the clinical study with the **BrainsWay** DTMS System. Although, in previous studies with the **BrainsWay** DTMS System, 7 seizures (out of over 300,000 treatment sessions) have been reported in subjects on high doses of psychotropic medications, which are known to increase the risk of a seizure, due to high alcohol consumption the night before treatment or due to other reasons. None of the subjects who have experienced DTMS-induced seizure have suffered lasting physical sequelae.

You should discuss with your doctor if you have had a seizure, or if you have a medical condition or change in a medical condition which may put you at increased risk of having a seizure, e.g., brain injury, change in medications, change in electrolyte balance, etc. Your doctor will decide if it is appropriate for you to receive **BrainsWay** DTMS treatment.

OCD Symptoms Improvement

BrainsWay DTMS treatment may require several weeks of treatment before symptom improvement occurs.

You should also inform your doctor if you have any behavioral changes, such as worsening of OCD symptoms, suicide

or irritability. Your family and caregiver should also be aware that if such behavioral changes appear, they should inform the treatment administrator immediately. Your doctor will determine whether **BrainsWay** DTMS treatment should be discontinued and, if so, what other treatment options are available.

Long-Term Safety

The long term safety of the **BrainsWay** DTMS treatment has been demonstrated in a clinical study. During the course of 6 weeks of ongoing treatment, the treatment was safely tolerated. Furthermore, no negative effects of treatment were seen during the study nor in follow up 4 weeks after the completion of treatment. Longer term effects of exposure to the DTMS treatment are not known. However, exposure to other devices (such as MRI scanners) with the same type and strength of magnetic fields produced by the **BrainsWay** DTMS coil are not associated with significant short-term or long-term safety concerns.

The safety and effectiveness of the **BrainsWay** DTMS System has not been established in the following patient populations or clinical conditions through a controlled clinical trial:

- Patients who have a suicide plan or have recently attempted suicide.
- Patients who do not meet the diagnostic criteria for obsessive compulsive disorder.
- Patients less than 22 years of age or older than 68 years of age.
- Patients with history of substance abuse or post-traumatic stress disorder.
- Patients with a psychotic disorder, including schizoaffective disorder, schizophrenic disorder, bipolar disease, or major depression with psychotic features.
- Patients with psychoses or with psychiatric emergencies where a rapid clinical response is needed, such as immediate suicide risk.
- Patients with neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma or with primary or secondary tumors in the CNS.
- Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents.
- Patients with implants controlled by physiological signals, including pacemakers, implantable cardioverter defibrillators, and vagus nerve stimulators.
- Patients who are pregnant or nursing.

During treatment with the Deep TMS System a loud clicking sound is emitted. Patients must use earplugs with a rating of at least 30 dB of noise reduction. There have been no reports of hearing loss with the Deep TMS treatment in the clinical study when earplugs were used.