BEACHES TMS
& BRAIN HEALTH
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Brainsway

Consent Form for Treatment with the Deep TMS System On and Off-Label Consent

This is the patient consent form for Deep Transcranial Magnetic Stimulation (dTMS) Therapy. This consent form outlines the treatment that your doctor has prescribed for you, the risks, potential benefits, and any alternative treatments if you decide not to be treated with dTMS.

What is dTMS?
Deep Transcranial Magnetic Stimulation (dTMS) is a noninvasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative to the brains neuronal pathways, the neurons in the relevant brain structure are activated.

Is it approved?
The Brainsway Deep TMS System is cleared by the Food and Drug Administration (FDA) for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder and Obsessive Compulive Disorder.

How does it work?
Your deep TMS treatment will be administered by certified BrainsWay technicians. When you arrive for treatment, your technician will help get you settled before getting you set up for treatment. Deep TMS treatment targets the region of your brain that has been associated with depression called the dorsolateral prefrontal cortex (DLPFC). After determining this specific location, your technician will administer a small magnetic pulse to stimulate movement in the thumb. With each pulse, you will hear a clicking sound and feel a small tapping sensation on your scalp - the "woodpecker" as we call it. Dr. Galliano and your technician will work slowly and adjust the power of the device accordingly to determine your unique motor threshold (MT), which is the least amount of power necessary to illicit a motor reflex response in the thumb. How often your motor threshold is re-evaluated will be determined by your physician. Typically, this value is determined at least once per week by your certified TMS technician.

After your power and intensity are determined, the magnetic coil will be adjusted to the predetermined treatment location and treatment will begin. Each treatment session lasts approximately 20 minutes for the Major Depressive Disorder (MDD) and Obsessive Compulsive Disorder (OCD) protocols. If you and the doctor have decided to complete the off-label Generalized Anxiety Disorder (GAD) protocol an additional 10-15 minutes will be to your total appointment time. Deep TMS treatment does not involve any anesthesia or sedation. You will remain awake and alert during the course of treatment. You may be evaluated by a healthcare provider during this treatment course.

Is the treatment effective?
The effectiveness of the Brainsway Deep TMS System has only been tested in patients receiving 5 daily sessions over a four-week course, and optional maintenance treatments with bi-weekly sessions for an additional 12 weeks, with the stimulation parameters outlined above. Any change in this treatment course, intensity, or location has not been tested, and efficacy results are not available.

Brainsway Deep TMS System is not effective for all patients with depression. Any signs or symptoms of worsening depression or signs of suicidality 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.

Are there any risks?
The most common adverse events reported are application site pain or discomfort and headache. If you experience these, we may be able to modify the location or intensity of the treatment, or you can use over-the-counter analgesics for relief.
Brainsway Deep TMS System is contraindicated for use in patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or that are non-removable. Failure to follow this restriction could result in serious injury or death. An object that may have this kind of metal includes, but is not necessarily limited to:

Aneurysm clips or stents
Implanted electrodes/stimulators
Ferromagnetic implants in ears or eyes
Cochlear implants

Brainsway Deep TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators.

If you have a removable device or object that may be affected by the magnetic field, the device should be removed from the patient area before treatment to prevent possible injury to the wearer or damage to the device. Examples include wearable monitors, bone growth stimulators, earrings, hearing aids, eyeglasses, jewelry, hair barrettes, cell phones, MP3 players, etc.
One seizure has been reported with the use of the dTMS device in the clinical study leading to Food and Drug Administration (FDA) approval. The seizure was reported in a patient who drank a significant amount of alcohol the day before treatment. Therefore, we advise that you refrain from alcohol consumption during the course of the treatment. Some patients may be at potential increased risk of seizure, including those with a history or family history of seizure or epilepsy, a history of stroke, head injury or trauma, presence of other neurological disease (CVA, cerebral aneurysm, dementia, increased ICP, or movement disorder), concurrent use of tricyclic antidepressants, neuroleptic medications, or other drugs known to lower the seizure threshold.

Long term effects of exposure to magnetic fields are not known. Due to the loud sound, earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction should be used during treatment. Brainsway Deep TMS System has not been studied in patients who have had no prior antidepressant medication.

What is Off-Label Device Use?

Off-label device use (OLDU) means using an FDA cleared device for a different condition, or using a device settings, that have not been specifically cleared by the FDA. OLDU is common, it occurs in every specialty of medicine. After a device has been cleared for one condition, clinicians are not limited to the FDA-approved indications and are allowed to use it for any condition if, in their professional judgment, it is reasonably safe and effective, and potential benefits outweigh potential risks in the clinician's determination.

Commonly used off-label uses for TMS include use for many other psychiatric diagnoses (Anxiety Disorders, tinnitus, Bipolar Disorders etc.), varying frequencies and amplitude of stimulation, varying positions on the head to stimulate different parts of the brain, shorter or extended protocols, more or less time between stimulation sessions, and/or bilateral treatments

I understand that my provider may recommend the off label use of TMS either initially or as an addition to my treatment later on. I accept the responsibility to ask as many questions as necessary to be sure I understand the potential benefits and risks. I understand that I can choose to consent for only the FDA approved protocol for TMS if I wish

Treatment may be considered off-label for the following reasons:

More or less than 5 treatments per week for 4 weeks
More or less than 1,980 pulses per treatment session
Initiation of bilateral protocol
More than 44 total treatments
dTMS prescribed for a diagnosis other than MDD or OCD
Insufficient antidepressant medication trial
I am younger than 22 years old
I am older than 70 years old

I have read the information contained in this Consent Form about Brainsway Deep TMS System and its potential risks and possible benefits. I have discussed this treatment with Dr. Galliano-Pardo and/or her designee/s, and all of my questions have been answered.

I have been educated about the potential off-label use of TMS and I understand that my course of dTMS treatment may be considered off-label for the reasons stated above.

I understand and acknowledge that off-label use of TMS is not covered by health insurance companies and there may be out of pocket expenses that I will be responsible for.

I understand that there are other treatment options that are considered safe and efficacious (medications, therapy, ECT, etc.). I further understand that no guarantee of any results has been made. I understand that if during the course of treatment, in the best judgment of the neuromodulation or medical staff, I require emergency treatment, I authorize and request that the said treatment be performed.

I understand that I can change my mind any time, and choose a different option. I voluntarily choose to receive dTMS Therapy with the Brainsway Deep TMS System and authorize Beaches TMS & Brain Health Inc, Alina M Galliano-Pardo MD PA, Dr. Galliano-Pardo and her staff to administer dTMS treatments to me.

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PRINTED NAME OF PATIENT

_____ _____
PATIENT SIGNATURE DATE

_____ _____
ALINA M GALLIANO-PARDO, MD DATE

_____ _____
GUARDIAN OR PARENT (if applicable) DATE

_____ _____
DESIGNEE (if applicable) DATE