ELEMENTAL CENTER LTD

15010 S RAVINIA AVE, STE 15, ORLAND PARK, IL 60462 | 1323 BUTTERFIELD RD, STE 116-118, DOWNERS GROVE, IL 60615 | 612 S WESTERN, UNIT 1, CHICAGO, IL 60612

Tel: 708-364-0580

Deep TMS Treatment (dTMS)- Medical Procedure Consent Form

Name of Physician: Martins Adeoye, MD, DFAPA

Name of Clinic: Elemental Center Ltd

Name of Patient: _____

My doctor has recommended that I receive treatment with Brainsway Deep transcranial magnetic stimulation (dTMS). This is a patient consent for a medical procedure called dTMS Treatment.

BrainsWay's revolutionary noninvasive treatment uses Deep Transcranial Magnetic Stimulation (dTMS) to safely and effectively target areas of the brain associated with MDD or OCD during 20 min treatment sessions — so you can live life to the fullest again.

This consent form outlines the nature of dTMS treatment, the risks of this treatment, the potential benefits of this treatment, and any alternative treatments that are available if I decide not to receive dTMS Treatment.

The information contained in this consent form is also described in the Depression or OCD Patient's Manual for Brainsway Deep repetitive transcranial magnetic stimulation. Not all information in the Manual is stated here, so you should read the Patient Manual and available materials provided by Brainsway and Elemental Center Ltd and discuss any questions that you have with your doctor or the Elemental Center staff. Once you have reviewed the manual and this consent form, be sure to ask your doctor or any of our staff at the Elemental Center Ltd any questions that you may have about DTMS Treatment.

WHAT IS dTMS?

dTMS is a non-invasive FDA-cleared medical procedure for the treatment of Major Depressive Disorder in adults. DTMS Treatment is a safe and effective treatment for patients with depression or OCD who have not benefitted from antidepressant or psychotropic medications.

dTMS is a brain stimulation technique that relies on the generation of brief magnetic fields using an insulated coil that is placed over the scalp. These magnetic fields are the same type and strength as those

used in magnetic resonance imaging (MRI) machines. The magnetic pulses generate a weak electrical current in the pre-frontal cortex region of the brain that briefly activates neural circuits at the stimulation site. dTMS has been shown to be a safe and well-tolerated procedure that can be an effective treatment for adult patients with depression who have not benefitted from anti-depressant medications.

The potential benefit of Brainsway's unique, patented technology is that it may lead to improvements in the symptoms of my psychiatric condition. I understand that not all patients respond equally well to dTMS. Like all forms of medical treatment, some patients recover quickly, others recover briefly and later relapse, while others may fail to have any response to dTMS.

Studies have shown the treatment to be effective for patients with MDD who have failed to respond to or couldn't tolerate medication. In real-life clinical settings, the treatment was proven to be effective for 3 out of 4 patients, with a 51% remission rate and a 75% response rate. BrainsWay's unique treatment and personalized protocol can provide relief for your depression symptoms.

ALTERNATIVES TO dTMS

I understand that there are alternative treatment options for my condition, including medications, psychotherapy, and electroconvulsive therapy (ECT). My doctor has explained to me the risks and benefits of these other options. My doctor has also explained why dTMS has been recommended for my specific case.

dTMS Treatment has been shown to be a safe and effective treatment for patients with certain mental disorders who have not benefitted from medication or other traditional treatments. The U.S. Food and Drug Administration (the "FDA") has permitted use of dTMS as a treatment for major depressive disorder and obsessive-compulsive disorder.

While the FDA may not have specifically approved the use of the dTMS system for other disorders, healthcare providers are permitted to use the treatment for an "unapproved" or "off-label" use when the provider considers such treatment is medically appropriate for the patient.

I understand that my treatment is for an ____approved ____off-label use (initial one) for the treatment of _____.

PROCEDURE

a. dTMS involves a series of treatments. For each dTMS session, I will be brought to a room, comfortably seated on a chair, and a cushioned helmet will be placed over my head. Before the beginning of the dTMS procedure, I will be asked to remove any metal or magnetic sensitive objects (e.g. jewelry, glasses, credit cards etc.). Because the DTMS Treatment system produces a loud click with each magnetic pulse I understand that I must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment for my comfort and safety. DTMS does not require anesthesia or sedation, so I will be awake and alert during the entire procedure.

b. The insulated magnetic coil gently placed over my head will be adjusted by staff / technician by delivering a series of pulses until it gives just enough energy so that my 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. This threshold could fluctuate depending on a variety of factors. How often my motor threshold will be re-evaluated will be determined by my doctor.

c. During the procedure, I will hear a clicking sound and feel a tapping sensation on my scalp. Once my motor threshold is determined, the helmet containing magnetic coil will be moved over a region of the brain that scientists think may be responsible for causing depression. I will receive a treatment as a series of "pulses" that lasts about two seconds, with a "rest" period of about 20 seconds between each pulse series. Treatment sessions typically last twenty to thirty minutes.

d. DTMS treatment session is conducted using a device called the dTMS Treatment 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. There is also a cooling system with the machine to cool the coil in case they get hot.

e. Specifically, DTMS Treatment has been shown to relieve depression symptoms in adult patients who have been treated with one antidepressant medication given at a high enough dose and for a long enough period of time but did not get better.

f. During a DTMS treatment session, the doctor or a member of their staff will place the magnetic helmet on my head after wearing appropriate size cap. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists think may be responsible for causing depression.

g. Next, once motor threshold is determined, and I will receive the treatment as a series of "pulses", with a "rest" period of about 20 seconds between each series. Treatment is to the left front side of my head and will take about 20-45 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 initially receive these treatments 5 times a week for 4 weeks (20 treatments) and I understand that additional treatments may be required in order to achieve maximum response. The treatment is designed to relieve my current symptoms of depression or OCD.

h. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations were reported by about one third of the patients who participated in the research studies. 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 in order to help make the procedure more comfortable for me. I also understand that headaches were reported in half of the patients who participated in the clinical trial for the device. I understand that both discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications such as acetaminophen if a headache occurs.

The DTMS Treatment System should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the 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 include:

- 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.

Seizures (sometimes called convulsions or fits) have been reported with the use of dDTMS devices.

I understand that I may discontinue treatment at any time.

NUMBER OF TREATMENTS

The exact number of treatments I receive cannot be predicted ahead of time. The number of treatments I receive will depend on my psychiatric condition, my response to treatment, the medical judgment of my psychiatrist, and insurance authorization approval. dTMS treatments are usually administered five times per week and I will likely receive these treatments daily for four to six weeks, and then possibly on a less frequent basis for several weeks thereafter. I will continue to be evaluated at regular intervals by my doctor during this treatment course. **Typically, patients who respond to dTMS experience results by the fourth to sixth week of treatment**. However, some patients may experience results in less time while others may take longer.

Potential Benefits of DTMS Treatment

a. My doctor has recommended DTMS treatment because it may lead to improvements in the symptoms of my mental disorder I understand that not all patients respond equally well to DTMS, and that some patients recover quickly, others recover briefly and later relapse, and others fail to experience any improvement from DTMS therapy.

b. I understand that most patients who benefit from DTMS Treatment experience results by the fourth week of treatment. Some patients may experience results in less time while others may take longer or may not benefit at all.

c. I understand that I may discontinue treatment at any time, although I will remain

RISKS OF TREATMENT

As with any medical treatment, there are certain risks involved in receiving dTMS treatment.

_____ a. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. It is also common to experience facial twitching as well as slight arm/hand twitching. I understand that I should inform the doctor or the DTMS staff if this occurs. The doctor or staff may then adjust the dose or make changes to where the coil is placed in order to help make the procedure more comfortable for me.

_____ b. I understand that it is common to experience headaches related to my treatment. Headaches typically get better over time and generally were relieved with over-the counter pain medications such as acetaminophen. It is also very common to feel fatigued after treatment.

_____ c. The dTMS Treatment System should not be used by anyone who has magnetic-sensitive metal in his or her head or that is within 12 inches of the magnetic coil and cannot be removed. Failure to follow this restriction could result in serious injury or death.

Objects that may have this kind of metal include:

- Aneurysm clips or coils
- Stents
- Implanted Stimulators
- Cardiac pacemakers or implantable cardioverter defibrillator
- 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 metallic or magnetic-sensitive ink.

_____ d. dTMS Treatment is not effective for all patients who suffer from depression/Ocd or other psychiatric conditions not FDA approved. If I or those around me notice any negative change in or worsening of my symptoms, or I experience mania or other new symptoms I will report them immediately to my doctor and/or the Elemental Center staff. I have been advised to ask a family member, friend or caregiver to monitor my symptoms to help me spot any signs that they have worsened.

_____ e. Occasionally, DTMS treatment causes seizures (sometimes called convulsions or fits) I will let my doctor know before my treatment if I have a history of a seizure disorder or if I experience a seizure at any time after my treatment.

_____ f. I understand that if the ear protection devices I must wear to protect my hearing should become loose or fall out during my treatment I will notify the person administering my treatment immediately.

_____ g. I understand that the risks of exposure to DTMS during pregnancy are unknown. I will inform my doctor before my treatment begins if there is any chance that I may be pregnant.

_____ h. I understand that there may be other unknown risks to the use of dTMS treatment and that

the long-term effects are not yet known.

_____ i. I understand that drinking alcohol, substances, other medications and lack of sleep may affect the motor threshold and could also affect the treatment response. I may have to do a drug screen in the office during the treatment. In event that such substances is determined to affect the treatment, the treatment could be canceled, delayed or postponed.

SAFETY & RISK INFORMATION

The safety of the Brainsway dTMS system was demonstrated in a clinical study involving 233 patients with moderate to severe Major Depressive Disorder. However, as with any other medical procedures and forms of treatment, Brainsway dTMS involves some risks and side effects. During the treatment, I may experience tapping, facial twitching, or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations are reported in about one third of patients. I understand that I should inform staff if this occurs.

The treatment staff may then adjust the stimulation settings or make changes to where the coil is placed in order to help make the procedure more comfortable for me. In addition, about half of patients experience headaches. Headaches were reported in 47% of the subjects participating in the clinical study. However, 36% of patients who had received a placebo treatment instead of dTMS also reported headaches, indicating that the headaches were not necessarily caused by the dTMS treatment. Application site pain and discomfort was reported in 25% and 20%, respectively, of those subjects participating in the clinical study. I understand that I should inform the dTMS technicians and my doctor if this occurs. The dTMS

helmet may be slightly adjusted on the head to relieve the pain or discomfort. Pain and discomfort associated with treatment usually gets better or goes away altogether with successive treatments.

The most serious known risk of dTMS is the production of a seizure. Although there have been a few case reports of seizures with the use of DTMS devices, the risk is extremely small. There was one case of seizure reported in Brainsway's FDA clinical study due to high alcohol consumption the night before, and three other cases of seizure were reported in other studies (out of approximately 50,000 treatment sessions) in cases of subjects who were on high doses of antidepressants. None of the subjects who have experienced seizure during dTMS treatment have suffered lasting physical sequelae. I understand that I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to treatment. I understand that I must discuss with my doctor if I have a history or family history of seizure/epilepsy or potential alteration in seizure threshold. This includes stroke, head/brain injury, change in medication, change in electrolyte balance, high intracranial pressure, severe headaches, presence of other neurologic disease(s) that may be associated with an altered seizure threshold, concurrent medication or other drugs that are known to lower the seizure threshold, secondary conditions that may significantly alter electrolyte balance or lower seizure threshold, or where a quantifiable motor threshold cannot be accurately determined.

Other side effects which may occur include possible hearing loss, pain in jaw, muscle twitching, anxiety, insomnia, retinal detachment, hypomania, and mania. I understand that I should inform my doctor if I experience any of these adverse events.

There are no known adverse cognitive (thinking and memory) effects associated with dTMS. There are no known long-term adverse effects reported with the use of dTMS.

However, as this is a relatively new treatment, there may be unforseen risks in the longterm that are currently unknown.

METAL IMPLANTS

dTMS should not be used by anyone who has non-removable magnetic-sensitive metal in their head or within twelve inches of the magnetic coil, with the exception of standard amalgam dental fillings. I understand that failure to follow restrictions could result in serious injury or death. Examples of restricted metal substances/objects include:

- Aneurysm clips or coils
- Stents in your neck or brain
- Implanted stimulators
- Cardiac pacemakers or implantable cardioverter defibrillator (ICD)
- Electrodes to monitor your brain activity
- Ear/eye ferromagnetic implants
- Metal ink in facial/head tattoos and permanent makeup
- Shrapnel or bullet fragments

There were no deaths in patients who took part in the clinical trial for Brainsway dTMS.

PATIENT VERIFICATION

____ I have read (or have had read to me) the information contained in this Medical Procedure Consent Form about Brainsway Deep TMS treatment, the process involved in the treatment and its potential risks. I understand there are other treatment options for my depression or OCD that are available to me and this have also been discussed with me. I have discussed with my doctor and the staff of the Elemental Center Ltd, who has answered all of my questions.

____ I understand that I am feel free to ask questions about dTMS at any time before, during, or after the course of treatment and that I may discontinue treatment at any time.

____ I give permission to the providers at the Elemental Center Ltd and the staff to administer this treatment to me.

____ I have been given a copy of this consent form to keep.

____ I understand there are other treatment options for my condition available to me and this has also been discussed with me.

____ I understand that DTMS is currently approved for depression, and OCD. However, if the goal of my treatment was for off-label indications, the treatment protocols and effects have been explained to me. My decision to receive DTMS treatment is being made on a voluntary basis. I understand I can withdraw my consent at any time and have the treatments stopped.

I, therefore, permit Dr Adeoye, the Elemental Center Ltd and its staff to administer this treatment to me.

Consent signed on _____, 20___ at _____ AM/PM

_____ _____

Signature of Patient | Printed Name of Patient

_____ _____

Signature of Provider/Witness | Printed Name of Provider/Witness