

NEED HELP WITH YOUR DEPRESSION? ARE YOUR CURRENT MEDS NOT WORKING?

Trial Information for Patients:

DTMS Center is recruiting patients who suffer from Major Depressive Disorder (MDD) and have not responded to antidepressant therapies to participate in a clinical study. The study is designed to evaluate the effectiveness of an investigational and drug-free therapy using Brainsway's Deep Transcranial Magnetic Stimulation (Deep TMS) device. The goal of the study is to compare a new investigational stimulation protocol to the FDA-cleared standard-of-care stimulation protocol. No one will receive sham or placebo treatment and you will not be charged for participating in the study.

What treatment would I receive?

All participants will be randomized into one of two groups: a treatment group and a control group. Participants in both groups will receive TMS with the Brainsway Deep TMS device. The treatment group will receive the investigational stimulation protocol; the control group will receive the FDA-cleared standard-of-care deep TMS stimulation protocol. The duration, frequency and treatment schedule will differ between both groups. Participants cannot choose if they are in the treatment or control group as group assignment is randomly generated. Regardless of treatment group, all patients will receive TMS at no cost.

Where is the study?

All study-related appointments and treatments will occur at 1601 Forum Place, Suite 1005, West Palm Beach FL 33401

How long is participation in the study?

Individuals in both groups will receive treatment over a course of 6 weeks.

Am I eligible?

You may be eligible to participate if you:

- Are between 22 and 86 years of age.
- Have a primary DSM-5 diagnosis of Major Depression.
- Have a minimum of 1 and a maximum of 4 antidepressant trials in the current episode.

In addition, you may be eligible if you do not:

- Endorse any previous or current psychotic or bipolar disorder.
- Have an active alcohol or substance use disorder.
- Have a current diagnosis of post-traumatic stress disorder.
- Possess ferromagnetic metals implanted in the head or neck.
- Have a personal or family history of seizures, not including febrile or ECT-induced seizures.

Individuals who are pregnant or breastfeeding are not eligible to participate in this study.

Additional Information

To view additional study details including complete inclusion/exclusion criteria, please visit the National Library of Medicine at clinicaltrials.gov/study/NCT06357832

Next steps

For questions, further information, or to learn about enrolling in the trial, contact Dr. Tendler or one of the staff at DTMS Center through one of the following methods:

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