

Potential Risks

Although DBS is generally a well-tolerated procedure, participation may expose you to some risks involved with the surgery and brain stimulation. All surgical risks are listed in the consent document and will be thoroughly discussed with you before you agree to any study procedures.

Possible Benefit

This is an investigational treatment and you may benefit from relief or decrease in your depression symptoms when the DBS system is turned on. It is possible that you do not get better from DBS.

Cost and Compensation

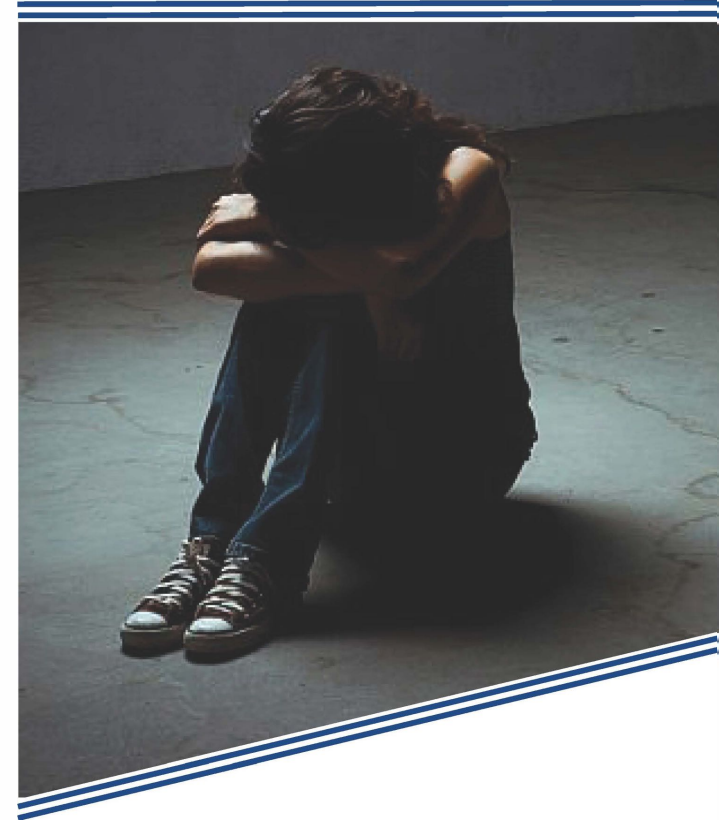
If you agree to take part in the study, all devices, surgeries, and medical care related to the DBS system will be covered by the study at no cost to you. You will also be compensated a modest amount for your time and travel expenses.

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Clinical Research Study: Deep Brain Stimulation for Treatment-Resistant Depression



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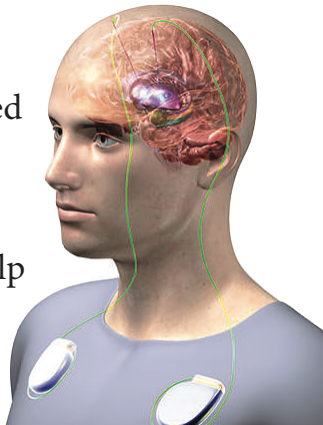
What is Treatment-Resistant Depression?

Treatment-Resistant Depression (TRD) is a severe form of depression that has not responded to several standard treatments. Major depression has a lifetime prevalence of about 15% across developed countries. Up to a third of patients fail to respond adequately to evidence-based treatments, including pharmacological, behavioral, and electroconvulsive therapy (ECT). Patients diagnosed with TRD may benefit from newer, investigational neurosurgical treatments.



What is Deep Brain Stimulation (DBS)?

Deep Brain Stimulation (DBS) is a surgical procedure where small electrodes are implanted into the brain, which provide electrical stimulation to specific areas of the brain to help patients control their depression symptoms. DBS is a common surgical treatment for movement disorders (i.e., Parkinson's Disease) and has been used to treat severe cases of depression.



Purpose of this study

The goal of this research study is to find ways to improve the treatment of TRD using DBS.



Inclusion Criteria

- Age between 22 and 70 years
- Diagnosed with treatment-resistant depression for at least 2 years
- Tried and did not respond to at least 4 medications/ treatments for depression
- Tried and did not respond to ECT or did not have sustained response to ECT

Exclusion Criteria

- Bipolar disorder with rapid cycling
- Diagnosed with psychotic disorder (e.g., schizophrenia)
- Drugs or alcohol abuse within the last 6 months (excluding nicotine)
- Suicide attempt within the last year
- Pregnant or plan on becoming pregnant in the next 2 years

What's Involved?

Medical & Psychiatric Evaluation

You will be asked detailed questions about your psychiatric and medical history, your current and past medications, and your response to previous treatments. You will also complete assessments of your mood, memory, and thinking.

Imaging & Lab Procedures

You will need to undergo lab tests, CT and MRI brain scans.

DBS Surgery and Hospital Testing

You will undergo surgery to place the DBS system and temporary brain monitoring probes. The DBS system and probes will be placed in brain regions that are known to be involved in depression and mood regulation. These procedures are commonly performed in patients with other neurological disorders like Parkinson's disorder and epilepsy. You will then stay in the hospital for 10 days undergoing testing and monitoring. The purpose of this testing is to allow the research team to understand how best to use the DBS system to treat your depression symptoms. Once the hospital testing is complete, the temporary monitoring probes will be removed, and you will go home.

DBS Therapy

Over the next year, you will receive DBS therapy to try to treat your depression. You will have regular follow-up appointments with the research team during this time. During these visits, the team will make adjustments to the DBS system to select the settings that best improve your symptoms. You will also be asked questions about your mood and undergo non-invasive tests like EEG (electroencephalogram – a test that detects electrical activity in your brain). The research team will test how well the DBS system is improving your symptoms.