Stimulating the brain, transforming lives.
Deep TMS stands for “Deep Transcranial Magnetic Stimulation”. Deep TMS is a non-invasive procedure, directing electromagnetic energy to a part of the brain called the Left Prefrontal Cortex. The stimulation activates the nerve cells in this governing, regulating center of the brain, with resulting improvement in depressive symptoms.

The stimulation is produced by a treatment coil contained in a helmet. The coil converts electrical energy to electromagnetic energy into a larger area and deeper into the brain than the previous rTMS technology. These magnetic fields are similar to those used in magnetic resonance imaging (MRI) systems. The magnetic field goes through the skull and induces a weak electrical current that briefly activates the nerve cells in this region of the brain and improves depressive symptoms.
Brainsway™ has created a new era in Depression treatment, offering a safe, effective, well-tolerated option. With Brainsway’s Deep TMS, patients can gain significant improvement in a relatively short time, without significant interruptions to their daily routine, and without suffering from systemic side effects.

**Brainsway Deep TMS Depression Treatment vs. Antidepressants & ECT**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Brainsway Deep TMS</th>
<th>Antidepressants</th>
<th>ECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>High even for severe, drug-resistant depression cases. Often also recommended for mild to moderate depression cases.</td>
<td>Efficacy substantially decreases with number of failed medication trials.</td>
<td>High – mostly recommended for severe depression cases.</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>Not required</td>
<td>Not required</td>
<td>Required</td>
</tr>
<tr>
<td>Side effects</td>
<td>The most common side effect is temporary, mild pain or discomfort in the area of the treatment site, which occurs during the treatment session. It typically occurs only during the first week of treatment. Other side effects may include muscle twitching and jaw pain.</td>
<td>The most common side effects include nausea, insomnia, anxiety, weight gain and sexual dysfunction, diarrhea, dry mouth, sweating.</td>
<td>Common side effects: Cognitive and memory dysfunction, alterations in blood pressure, pain and discomfort. Rare side effects: Adverse reactions to anesthesia, cardiovascular complications, death.</td>
</tr>
<tr>
<td>Session length</td>
<td>20 minutes</td>
<td>Not Applicable</td>
<td>Several hours, including anesthesia and recovery</td>
</tr>
<tr>
<td>Overall treatment term</td>
<td>20 sessions in the acute phase</td>
<td>Generally antidepressants are prescribed for an Indefinite or indefinite period.</td>
<td>Typically 6-12 sessions, in the acute phase.</td>
</tr>
<tr>
<td>Procedure</td>
<td>Brief, non-invasive electromagnetic stimulation of brain regions</td>
<td>Requires daily adherence</td>
<td>Electrically induced seizures</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>None</td>
<td>Oftentimes requires partial hospitalization (day hospital).</td>
<td></td>
</tr>
<tr>
<td>Recovery time after each session</td>
<td>Minutes – patient can drive home independently</td>
<td>None</td>
<td>Hours to days</td>
</tr>
<tr>
<td>Clinical results achieved in</td>
<td>4-6 weeks [1,3,4]</td>
<td>2-4 weeks</td>
<td></td>
</tr>
</tbody>
</table>


**Brainsway Deep TMS Depression Treatment vs. Surface TMS**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Brainsway Deep TMS</th>
<th>Surface TMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>Over 32% remission rates achieved after 4 weeks of acute treatment in the Brainway pivotal study.</td>
<td>9% remission rates achieved after 4 weeks of acute treatment in a surface TMS pivotal study.</td>
</tr>
<tr>
<td>Session Length</td>
<td>20 minutes</td>
<td>37 minutes</td>
</tr>
<tr>
<td>Overall treatment term</td>
<td>400-600 minutes</td>
<td>740-1110 minutes</td>
</tr>
</tbody>
</table>

Note: The Deep TMS depression treatment and Surface TMS depression treatment were not compared in head to head studies.

The StarT³ study demonstrated a 40% response rate to an initial antidepressant trial and only a further 10% increased rate with each of three additional trials.

**Surface TMS –** The magnetic pulse of the Surface TMS system is able to directly stimulate the brain up to a depth of approximately 1.5 cm below the surface.

**Brainsway Deep TMS –** The magnetic pulse of the Brainsway Deep TMS system is able to directly stimulate deeper into the brain (up to 8 cm) than the Surface System.

**Brainsway Deep TMS**

Brainsway™ Deep TMS Depression

Treatment vs. Traditional Therapy

Find out if Brainsway Deep TMS is right for you. Contact Yellowbrick’s Center for Clinical Neuroscience at 866.364.2300 x233.
The FDA and the CE have approved Brainsway Deep TMS for treatment of a wide range of patients, suffering from mild to severe and persistent depression, who did not improve following the use of any number of antidepressants (in the current depressive episode).

The FDA indication is based on a unique long-term 16-week Double-Blind Placebo-Controlled Multi-Center study which enrolled over 230 subjects, showing a profound decline in HDRS-21 and significant remission (32.6%) and response (38.4%) rates at the primary endpoint of the study. In the study, Brainsway’s treatment was proven to be safe, and the treatment was well tolerated by the majority of the study subjects.

Brainsway’s treatment has been proven safe and effective, and has no known long-term side effects and no systemic effects (effects deriving from medication entering the bloodstream and circulating throughout the body). The most common side effects are headaches and local discomfort, both usually temporary and mild.

There were no deaths or serious injuries 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.

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

When Should the Brainsway Deep TMS Treatment Not be Used?

Deep TMS Treatment delivers a magnetic field that could cause any metal objects that are near the device to move or to get hot. Deep TMS Treatment should not be used in patients with metal implants in or around the head (except for standard amalgam dental fillings).

Deep TMS Treatment should not be used if you have implanted electronic devices in your body. These implants could cause serious injury or death if Deep TMS Treatment is used.

During the initial treatment phase, Deep TMS sessions were performed daily for 4 weeks and during the maintenance phase, subjects were treated twice a week for another 12 weeks.

The primary endpoint was the change from baseline (i.e., the starting score before treatment) in a standard scale for measuring depression symptoms, known as the Hamilton Depression Rating Scale (HDRS). The model estimated mean change from baseline in HDRS scores in the Deep TMS group across 5 weeks compared to the sham group was statistically significant. The response rate (meaning the percent of patients who had a reduction in HDRS scores of at least 50%) was significantly better in the Deep TMS group compared to the sham group. The remission rate (meaning the percent of patients who had a reduction in HDRS score to less than 10 points) was significantly better in the Deep TMS group compared to the sham group.

There was a statistically significant improvement in quality of life in patients treated with the Deep TMS treatment, according to the difference in Q-LES-Q scores between the Deep TMS and sham groups.
Yellowbrick is a national center of excellence specializing in the treatment of emerging adults (ages 18-30) and their families. Across a spectrum of diagnoses and syndrome patterns of dysfunction, all of the young people coming to Yellowbrick from across the United States share the common difficulty in negotiating the universal challenges of transition to adulthood. Yellowbrick’s treatment model facilitates the adaptive maturation of emerging adults’ brains and minds with interventions informed by an integration of:

- Neuroscience research
- Developmental psychology
- Cognitive, experiential and in-depth interpersonal psychotherapies
- Strength-based rehabilitation approaches and cognitive enhancement
- Sober peer community