

Stimulating  
the brain,  
Transforming  
lives.



Brainsway

**YELLOWBRICK**<sup>SM</sup>

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# Stimulating Hope

Breakthrough Unique & Effective Treatment for Depression

## Brainsway *Deep* Transcranial Magnetic Stimulation System for Treatment of Major Depression

Major Depressive Disorder painfully affects nearly 15 million American adults annually. It is the leading medical condition contributing to suicide and worldwide disability.

Patients suffering from Major Depressive Disorder are traditionally treated with antidepressant medications. However, too often, antidepressants fail to bring the hoped-for relief, and frequently cause adverse side effects. Brainsway *Deep* TMS is FDA approved for treatment of depression in patients who have failed one trial of an antidepressant. Brainsway *Deep* TMS performs deep but safe, non-invasive brain stimulation using directed electromagnetic fields which promote neuronal regulation and regeneration.

Brainsway's *Deep* TMS technology is based on patents filed by the U.S. National Institutes of Health (NIH). Brainsway *Deep* TMS treatment has been enthusiastically embraced by the international academic community, with superior results published in peer reviewed journals from over 60 clinical trials in premier medical centers worldwide.

Yellowbrick and Brainsway are partnering to be the first to bring this innovative & effective treatment for depression to Chicago. Yellowbrick is a primary investigator site for clinical research trials exploring additional FDA indications for this National Institute of Mental Health patented technology.

## Brief Treatment, Long Term Effect

### How Does Brainsway *Deep* TMS Treatment Work?

*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. The Brainsway *Deep* TMS "H" coil directs this 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.

## Treatment Session

In each session, the patient is comfortably seated on a chair, and a cushioned helmet is gently placed over the head. The procedure requires daily sessions of 20 minutes over 4-5 weeks. There are usually no significant adverse effects and patients are able to immediately engage fully in their lives.

# Brainsway Advantage

## Brainsway *Deep* TMS Depression Treatment vs. Traditional Therapy

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.

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 Depression Treatment vs. Antidepressants & ECT

Parameter	Brainsway <i>Deep</i> TMS	Antidepressants	ECT
Efficacy	High even for severe, drug-resistant depression cases. <sup>1</sup> Often also recommended for mild to moderate depression cases.	Efficacy substantially decreases with number of failed medication trials <sup>2</sup>	High – mostly recommended for severe depression cases
Anesthesia	Not required	Not required	Required
Side effects	The most common side effect is temporary, mild pain or discomfort in the area of the treatment site, which occurs during the treatment session. This typically occurs only during the first week of treatment. Other side effects may include muscle twitching and jaw pain <sup>1,3-5</sup>	The most common side effects <sup>6</sup> include nausea, insomnia, anxiety, weight gain and sexual dysfunction, diarrhea, dry mouth, sweating.	Common side effects: Cognitive and memory dysfunction, alterations in blood pressure, pain and discomfort. Rare side effects: Adverse reactions to anesthesia, cardiovascular complications, death <sup>7</sup>
Session length	20 minutes	Not Applicable	Several hours, including anesthesia and recovery
Overall treatment term	20 sessions in the acute phase	Generally antidepressants are prescribed for an Indefinite or permanent period.	Typically 6-12 sessions, in the acute phase
Procedure	Brief, non-invasive electromagnetic stimulation of brain regions	Requires daily adherence	Electrically induced seizures
Hospitalization	None	None	Often requires partial hospitalization (day hospital)
Recovery time after each session	Minutes – patient can drive home independently	None	Hours to days
Clinical results achieved in	2-4 weeks <sup>1,3-5</sup>	4-6 weeks	2-4 weeks

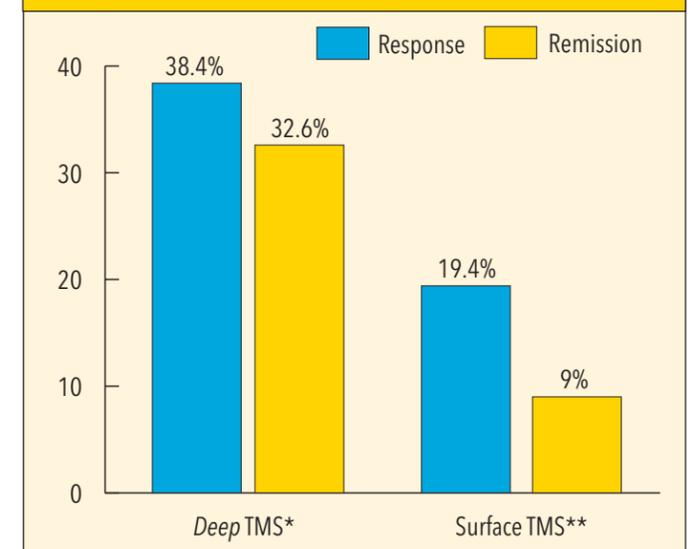
Brainsway *Deep* TMS Depression Treatment vs. Surface TMS

Parameter	Brainsway <i>Deep</i> TMS	Surface TMS
Efficacy	Over 32% remission rates achieved after 4 weeks of acute treatment in the Brainsway pivotal study <sup>1</sup>	9% remission rates achieved after 4 weeks of acute treatment in a surface TMS pivotal study <sup>8</sup>
Session Length	20 minutes	37 minutes
Overall treatment term	400-600 minutes	740-1110 minutes

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

The StarD<sup>2</sup> study demonstrated a 40% response rate to an initial antidepressant trial and only a further 10% increased rate with each of three additional trials.

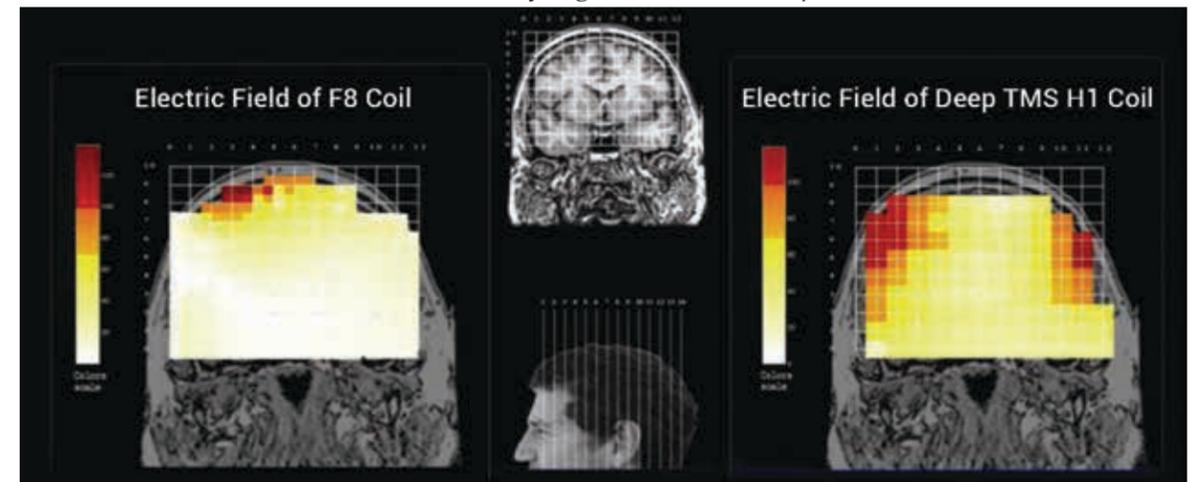
Comparison of Treatment Efficacy - Real Treatment Group



\* Results of 212-patient Deep TMS DBPC Multi-center study using Brainsway's device (Study led to FDA approval for the device)

\*\* Results of 300-patient study using Neuronetics' device published by Oreardon et al. in the Journal of Biological Psychiatry in December 2007 (Study led to FDA approval for the device)

Electric Fields Generated by Figure 8 Coil vs. *Deep* TMS H1 Coil



Find out if Brainsway *Deep* TMS is right for you. Contact Yellowbrick's Center for Clinical Neuroscience at 866.364.2300 x233.

1 Levkovitz Y et al. Efficacy and safety of deep transcranial magnetic stimulation for major depression: a prospective, multi-center, randomized, controlled trial. *World Psychiatry* 2014; February 2015.

2 Rush AJ, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR\*D report. *Am J Psychiatry*. 2006;163:1905-1917.

3 Levkovitz Y, Harel EV, Roth Y, Braw Y, Sheer A Katz L, Gersner R and Zangen A. (2009) Deep transcranial magnetic stimulation of the prefrontal cortex – Effectiveness in major depression. *Brain Stimulation* 2: 188-200.

4 Isserles M, Rosenberg O, Dannon P, Lerer B and Zangen A (2011) Cognitive emotional reactivation during deep transcranial magnetic stimulation over the prefrontal cortex of depressive patients affects antidepressant outcomes. *Journal of Affective Disorders* 128: 235-242.

5 Harel EV, Rabany L, Deutsch L, Bloch Y, Zangen A, Levkovitz Y. H-coil repetitive transcranial magnetic stimulation for treatment resistant major depressive disorder: An 18-week continuation safety and feasibility study. *World J Biol Psychiatry* 2014;15(4):298-306.

6 Fabbri C, Marsano A, Balestri M, De Ronchi D, Serretti A. Clinical features and drug induced side effects in early versus late antidepressant responders. *J Psychiatr Res* 2013;47(10):1309-1318.

7 Lawrence Park, AM, MD. (2011). Risks and Side Effects of ECT. *Psych Central*. Retrieved on December 3, 2014, from <http://psychcentral.com/lib/risks-and-side-effects-of-ect/0007365>

8 O'Reardon JP, Solvason HB, Janicak PG, et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial. *Biol Psychiatry* 2007;62:1208-1216.

# Certified & Safe

## Brainsway *Deep* TMS Treatment Safety Information

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.



More than 20 International Trial Sites

# Clinically Tested and Proven

## Treatment Effectiveness Information

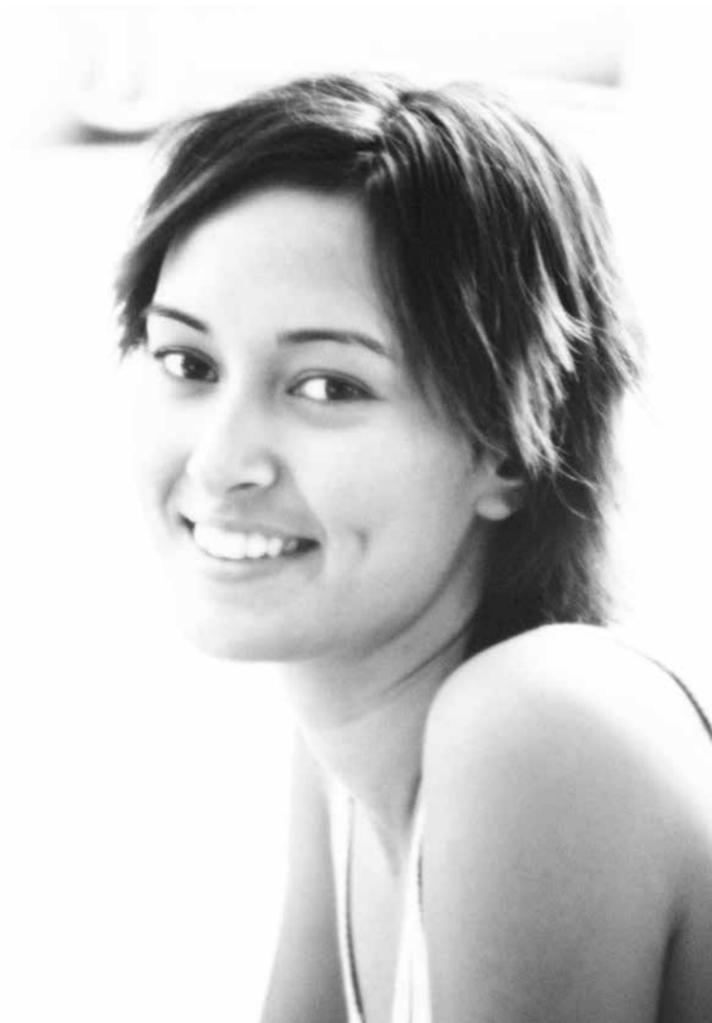
The safety and effectiveness of the Brainsway *Deep* TMS System for treatment of Major Depressive Disorder was demonstrated in a prospective, double blind, randomized, controlled, multi-center trial. The study was conducted at 20 study sites in the United States (15 sites), Israel (5 sites), Germany (2 sites) and Canada (1 site).

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.

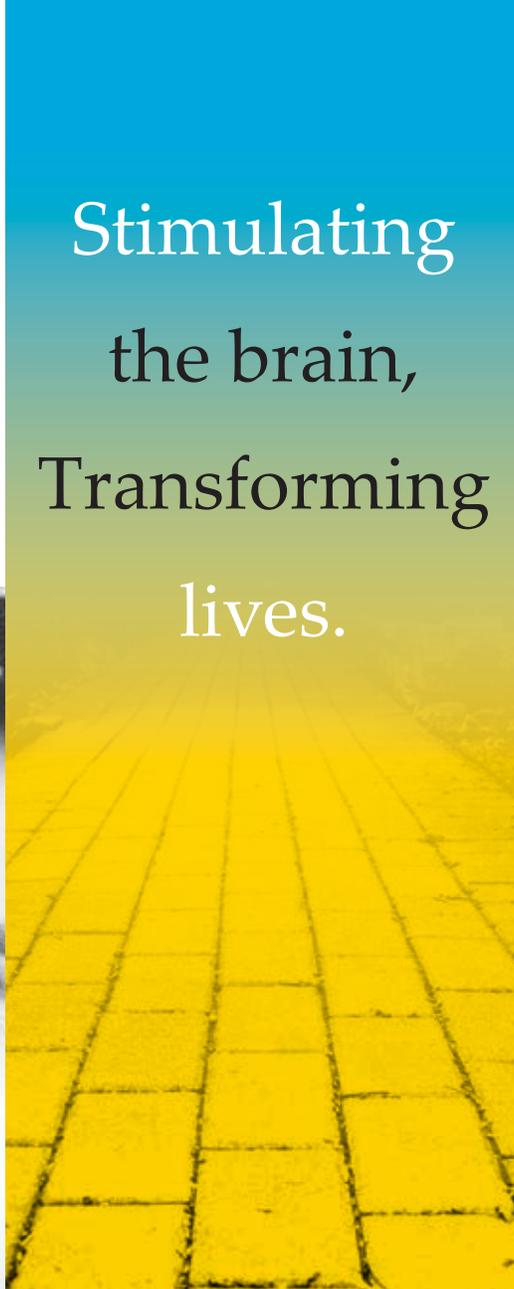
The primary endpoint was the change from baseline (i.e., the starting score before treatment) in a standard scale for measuring depression symptoms, known as the Hamilton Depression Rating Scale (HDRS). The model estimated mean change from baseline in HDRS scores in the *Deep* TMS group across 5 weeks 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.

The efficacy of the *Deep* TMS Treatment was still seen at 16 weeks, based on a statistically significant change from baseline.



# Stimulating the brain, Transforming lives.



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

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