



BREAKTHROUGH EFFECTIVE TREATMENT FOR DEPRESSION PATIENTS

Have Antidepressants Failed to Achieve Results for Your Patients?

Major depressive disorder has traditionally been treated with anti-depressants.

However, research demonstrates that anti-depressants have failed to achieve satisfactory results for many patients¹.

The patented breakthrough technology of Brainsway* unfolds a new dawn in depression treatment. The company offers a clinically-proven solution for various categories of depression patients, ranging from mild to severe depression cases, who failed to achieve sufficient outcomes from existing treatments in the current episode.

The treatment performs deep non-invasive brain stimulation using directed electromagnetic fields, generating significant improvement in the depressive symptoms.

Brainsway's technology is based on patents filed by the U.S. National Institutes of Health (NIH) and the company. The treatment has been enthusiastically embraced by the international academic community, with over 60 clinical trials in leading institutions worldwide, for psychiatric and neurological indications.



Brainsway

Effective Treatment

Brainsway Deep TMS has many advantages over traditional depression treatments.

The efficacy of antidepressants decreases with the number of failed medication trials¹, and they also entail systemic side effects² which lead many patients to neglect their medication regime. Other alternatives, such as Electroconvulsive Therapy (ECT), require anesthesia and may entail significant risks and side effects.

Therefore, in many cases, depression patients have been virtually trapped in their condition with limited solutions.

Brainsway's novel Deep TMS (Deep Transcranial Magnetic Stimulation) technology holds a variety of benefits for depression patients. In addition to its noninvasive stimulation of deep brain regions and efficacy, the treatment involves no hospitalization, typically requiring only brief 20-minute daily sessions over a period of 4-6 weeks. Clinical trials that led to Brainsway's FDA clearance demonstrated excellent results using 33% less treatment sessions, with sessions which are almost 50% shorter than other forms of TMS technology.

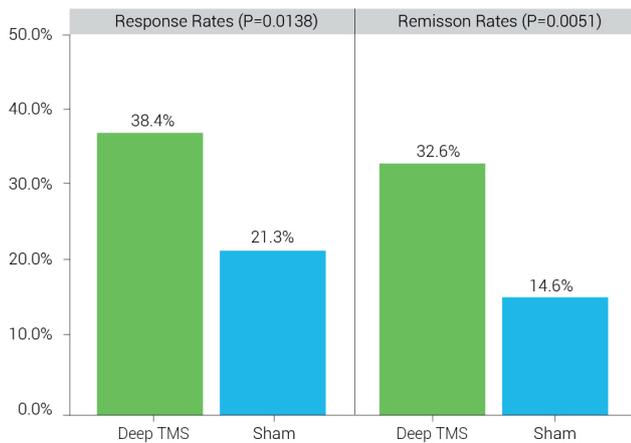
Moreover, Deep TMS has no systemic side effects^{3-5,6}. It is also highly convenient, as it can be administered in clinics of any size.

Clinically Proven, Certified and Safe

The FDA⁷ 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).

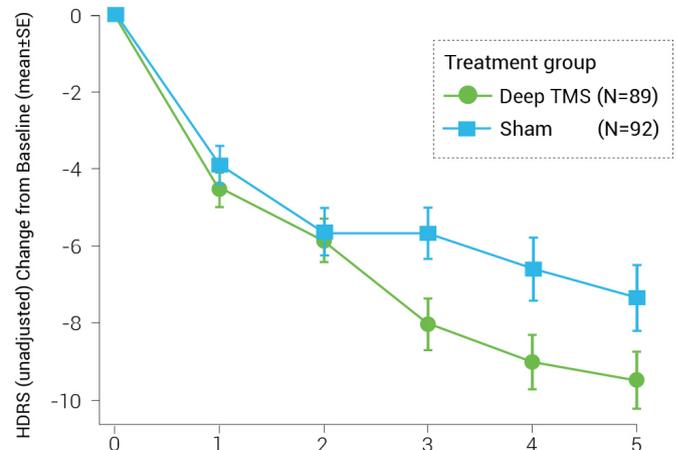
The FDA indication is based on a unique long-term 16-week double-blind placebo-controlled multi-center study which enrolled over 230 subjects, showing a profound decline in HDRS-21 and significant remission (32.6%) and response (38.4%) rates at the primary endpoint of the study. In the study, Brainsway's treatment was proven to be safe, and the treatment was well tolerated by the majority of the study subjects⁶.

Response and Remission Rates at Week 5*



* Remission – HDRS-21 Score < 10,
Response – Improvement of at least 50% from baseline

HDRS-21 Score Over Time



Slope (adjusted) of Change Deep TMS = -6.39 points
Slope (adjusted) of Change Sham = -3.28 points
P-value of Difference = 0.0080

1. 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.
2. 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.
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 Q, 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. Levkovitz Y, et al. Efficacy and safety of deep transcranial magnetic stimulation for major depression: a prospective, multi-center, randomized, controlled trial. *World Psychiatry* 2015; Vol.14, 64-73.
7. FDA 510(k) No. K122288



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