

# Low-Field Synchronized Transcranial Magnetic Stimulation (sTMS) for Treatment of Depression: Results from an Open-label Extension Study



Mahendra T. Bhati, M.D.<sup>1</sup>, Michael E. Thase, M.D.<sup>2</sup>, Jonathan L. Bissett, B.S.<sup>3</sup>, Joseph M. Massaro, Ph.D.<sup>4</sup>, Andrew F. Leuchter, M.D.<sup>5</sup>

## INTRODUCTION:

sTMS uses rotating magnets to deliver low-field stimulation synchronized to an individual's alpha EEG frequency. Studies show significant antidepressant effects after 4-6 weeks of sTMS (20-30 treatments). This study examined response to sTMS in subjects who completed a six-week double-blind randomized sham-controlled sTMS trial and entered a four-week open-label extension phase. We hypothesized that subjects who had received prior sham treatment would show a greater improvement of symptoms during open-label than those who had received prior active treatment (20 vs. 50 total treatments).

## METHODS:

92 medication-free subjects failed to reach remission in the sham-controlled trial and entered a subsequent four-week open-label phase (20 treatments). 47 previously received active sTMS and 45 sham sTMS. 83 subjects completed all 10 weeks. Depression severity was assessed weekly using the 17-item Hamilton Depression Rating Scale (HamD<sub>17</sub>).

## RESULTS:

Subjects who previously received active sTMS had lower mean HamD<sub>17</sub> scores at the start of the open-label phase versus those receiving sham (14.49 vs. 16.59,  $P = 0.054$ ). Both groups demonstrated sustained and significant reductions in HamD<sub>17</sub> when compared to baseline ( $P < 0.001$ ), with no significant differences between groups. For patients with a history of antidepressant treatment-resistance (failure to respond to at least one antidepressant medication), those who received prior sham treatment showed greater reduction in HamD<sub>17</sub> scores after 20 open-label sTMS treatment sessions when compared with patients who previously received active sTMS (-5.12 vs. -1.70,  $P = 0.027$ ).

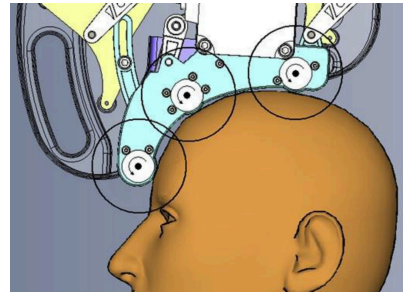


Figure 1. sTMS device with rotating magnets.



	rTMS	NeoSync sTMS® with NEST
Magnetic field generation	High current (~1000A) passing through a coil	Rotating permanent magnets
Magnetic field strength	4.0 Tesla	0.38 Tesla
Neuronal activation	Active (direct)	Modulation (indirect)
Pulse frequency	10 Hz	Set to patient's alpha (intrinsic) frequency based on EEG (8-13Hz)
Waveform		
Mechanism of action	Intense magnetic pulse above motor threshold generates neuronal action potential to cause neuronal firing in an area of the pre-frontal cortex	Low intensity sinusoidal waveform to influence neuronal activity using low energy magnetic fields at the patient's natural resonant frequency.

Figure 2. Comparison between rTMS and sTMS.

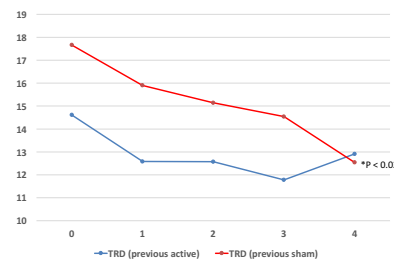


Figure 3. Weekly change in HamD<sub>17</sub> for TRD subjects getting open-label sTMS.

## DISCUSSION:

Subjects who did not enter remission prior to open-label sTMS treatment showed further reduction in depression symptoms with greater separation between previously treated sham patients with a history of antidepressant medication treatment-resistance versus similar patients who previously received active sTMS. Continuation of sTMS for up to 10 weeks (50 treatments) appears to benefit some patients and was well tolerated. It is unclear whether there is benefit for all subjects with greater than 30 sTMS treatments.

## CONCLUSION:

sTMS is a safe and promising treatment for major depression. Sham-controlled and open-label data suggest that 20-30 treatments with sTMS alone may be beneficial for patients with depression and uniquely effective for treatment-resistant depression. sTMS offers a potential new form of TMS for treatment of depression.

## Reference:

Leuchter AF, et al. Efficacy and Safety of Low-Field Synchronized Transcranial Magnetic Stimulation (sTMS) for Treatment of Major Depression. *Brain Stimulation*. 2015 8(4): 787-94.

## Study Sponsor: NeoSync, Inc.

## Author Affiliations:

1. Departments of Psychiatry and Neurosurgery, Stanford University School of Medicine
2. Department of Psychiatry, Perelman School of Medicine, University of Pennsylvania
3. NeoSync, Inc., Newton, MA
4. Department of Biostatistics, Boston University School of Public Health
5. Department of Psychiatry, David Geffen School of Medicine, University of California Los Angeles