

Wisconsin Public Psychiatry Network Teleconference (WPPNT)

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Transcranial Magnetic Stimulation: TMS

A proven non-drug treatment for depression

Presented by:
Dr. Leslie Taylor, MD
& Ian Cox

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NEURONETICS

TMS Center of Madison

- Opened in January of 2013
- Collaboration between Rosecrance and Connections Counseling



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Understanding the Problem

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Major Depression: A Large Patient Population Currently Being Underserved



Kessler RC et al. JAMA. 2003;289(23):3095-3105. 2012 United States Census Bureau. <<http://www.census.gov>>

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Top 10 Causes of Disability A Major Burden for Society Today

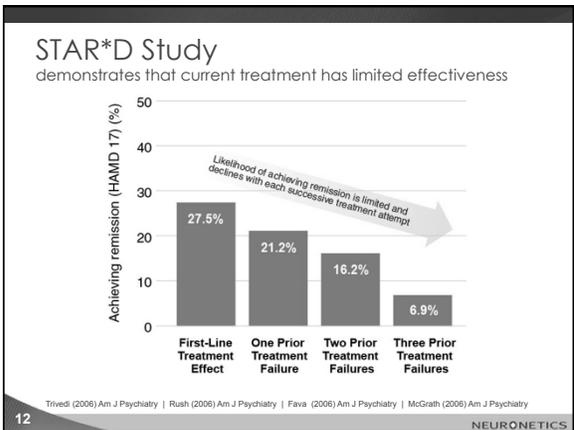
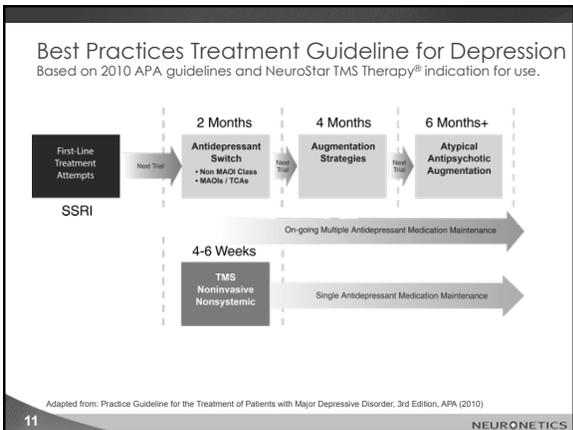
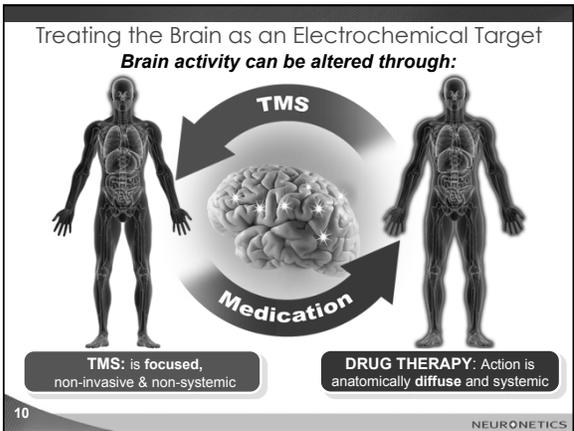
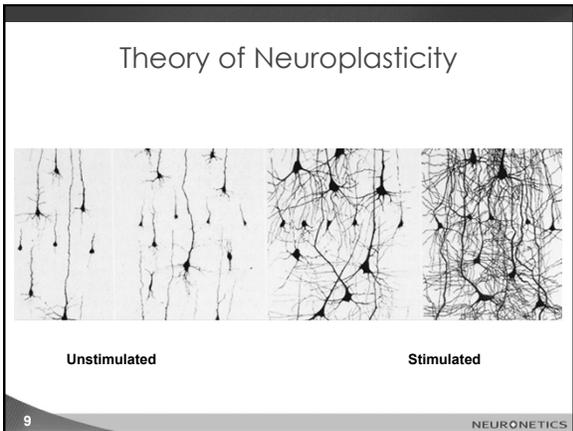
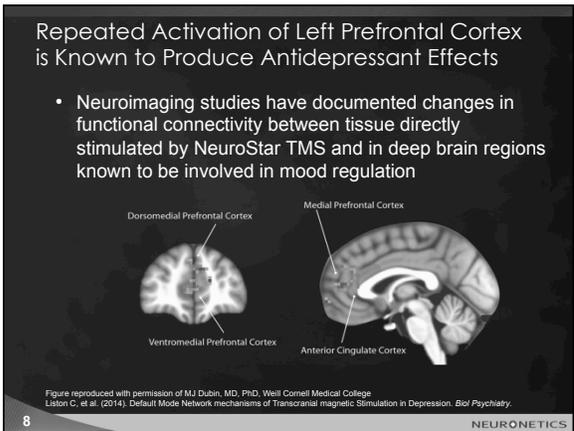
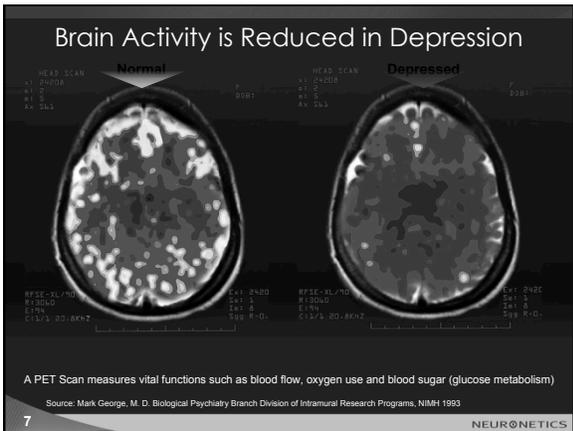
1. Lower Respiratory Infections
2. Diarrheal
3. **Unipolar Major Depression**
4. Ischemic Heart Disease
5. HIV/AIDS
6. Cerebrovascular Disease
7. Premature Birth
8. Birth Trauma
9. Road Traffic Accidents
10. Neonatal Infections

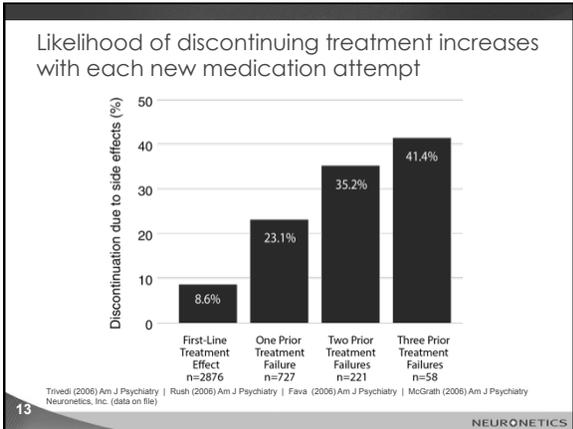


The World Health Organization. The World Health Report 2004: Changing History. Annex Table 3: Burden of disease in DALYs by cause. Geneva: WHO, 2004.

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TMS Therapy Avoids the System Side Effects Commonly Experienced with Antidepressant Medications

TMS Side Effects

- Scalp Pain or Discomfort at Treatment Site

Systemic Drug Side Effects

- Weight Gain
- Constipation
- Diarrhea
- Nausea
- Drowsiness
- Insomnia
- Nervousness
- Anxiety
- Increased Appetite
- Decreased Appetite
- Decreased Sexual Interest
- Weakness
- Dry Mouth
- Dizziness
- Fatigue
- Headache/ Migraine
- Abnormal Ejaculation
- Impotence
- Sweating
- Tremor
- Treatment Discontinuation Side Effects

Adverse Events occurring at an incidence >5% and 2x the rate of placebo treatment

Janicak, et al. Transcranial Magnetic Stimulation in the treatment of major depression: A comprehensive summary of safety experience from acute exposure, extended exposure, and during reintroduction treatment. J Clin Psychiatry. 2008; Neuronetics, Inc. (data on file)

Primary Differences: TMS vs ECT

TMS	ECT
<ul style="list-style-type: none"> • Non-invasive • Minimal Side Effects • No Seizure • Active participant during the session • Brief Interruption in one's day 	<ul style="list-style-type: none"> • Invasive • Significant Risk of Side Effects • Seizure Required • Anesthesia Required • Cannot Drive afterwards

NeuroStar TMS Therapy® System

- **Cleared in October 2008 by the FDA for the treatment of patients with major depression.**
- Utilizes a highly focused **MRI-strength magnet** to stimulate nerve cells in an area of the brain thought to control mood.
- Stimulating these neurons, causing the release of neurotransmitters and clinical effects.

TMS in Clinical Practice

- Non-invasive
- No anesthesia or sedation
- No systemic side effects
- No negative impact on cognition
- Tolerable treatment with less than 5% discontinuation rate
- 37 minute outpatient procedure easily performed in a physician's office
- 6 week treatment course
- Antidepressant medications may still be used during TMS treatments

PATENTED IRON CORE COIL

Precision Pulse TMS® Technology

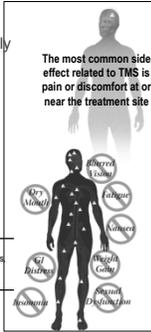
- Targeted stimulation of the prefrontal cortex that activates deeper brain regions
- Flexible product design allows for high volume clinical use across a broad range of depression patient profiles

Releases neurotransmitters
Increases cerebral blood flow
Increases glucose metabolism

Proven Safety and Tolerability Profile

- Non-systemic, avoids the side effects commonly associated with antidepressant medications
 - » No adverse effect on cognition
 - » No adverse effect on sleep
- Excellent treatment adherence with less than 5% discontinuation rate due to adverse events
- Post marketing experience confirms a rare risk of seizure with NeuroStar TMS (<0.1% per patient)

The most common side effect related to TMS is pain or discomfort at or near the treatment site



MEDICATIONS: Other adverse events are nervousness, weakness, abnormal ejaculation, constipation, anxiety, impotence, diarrhea, increased appetite, dizziness, sweating, decreased appetite, tremor, drowsiness, decreased sexual interest, headache/migraine, blurred vision, and treatment discontinuation side effects.
NEUROSTAR: Eye pain, toothache, muscle twitching, facial pain, pain of skin.

Janicak PG, et al. (2008). J Clin Psychiatry. Product Labeling for currently marketed antidepressants (Neuronetics, Inc., data on file).

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NeuroStar TMS Therapy® System

Precision Pulse TMS®

Patented Iron Core Coil
Efficiently transfers electrical energy into magnetic field for uninterrupted treatment.

Iron Core Coil
Designed for therapeutic use in multiple clinical practice settings.

3D Coil Positioning System
Provides accurate and repeatable Treatment Coil position while providing the patient a comfortable head support.

Precision Pulse TMS
Provides targeted stimulation of the prefrontal cortex that activates deeper brain regions.

Coil and Head Support
Supports the Treatment Coil and accurately maintains position throughout treatment, reducing the burden on the system operator.

Graphical User Interface
Intuitive system software guides the system operator through step-by-step treatment workflow.

MT Assist®
Unique software makes finding the right treatment dose easy.

Treatment Chair
Provides comfortable patient seating during treatment sessions.

TMS TrakStar®

Patient Data Management System
Automatically captures all Motor Threshold and treatment information.

Centralized Database
Manages all NeuroStar patient data.

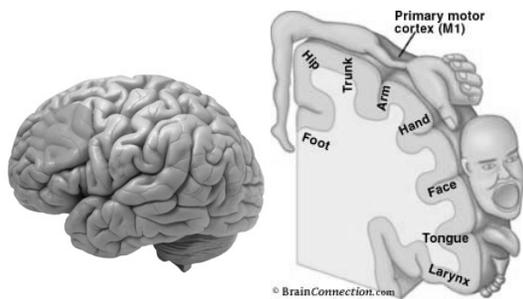
Custom Reports
Improves outcomes tracking.

Web-enabled Technology
Accesses data from multiple systems and locations.

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Individualized Treatment



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USNews
...the use of an electromagnet to treat severe depression deserves a term that researchers hate to use: **breakthrough.**

TIME Global Business
10 Start-Ups That Will Change Your Life

WALL STREET JOURNAL
A New Approach to Treating Intractable Cases of Depression

OZ
Home

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Top Behavioral Health Hospitals Provide TMS Therapy

- Johns Hopkins Hospital
- Mayo Clinic
- McLean Hospital, Belmont, Mass.
- New York-Presbyterian University Hospital of Columbia and Cornell
- UCLA Semel Institute for Neuroscience & Human Behavior
- McLean Hospital
- Sheppard and Enoch Pratt Hospital

BEST HOSPITALS
NATIONAL
RANKED IN 6 SPECIALTIES
2014-15

Other notable hospitals and institutions include:

- Resonance Allen Center for Noninvasive Brain Stimulation (Beth Israel OMC)
- Medical University of South Carolina
- Butler Hospital/Brown University
- Stanford Hospital
- Florida Hospital
- University of Michigan
- Rush University
- University of Florida
- Boston University
- University of South Florida
- Southern Illinois University
- Walter Reed National Military Medical Center

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Proven Efficacy Demonstrated Through Randomized Controlled Trials

Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression:
A Multisite Randomized Controlled Trial

Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder:
A Sham-Controlled Randomized Trial

Sponsored by the National Institute of Mental Health (NIMH)

In an NIMH-funded, independent, randomized controlled trial, patients treated with TMS using the NeuroStar TMS System were four times more likely to achieve remission compared to patients receiving sham treatment ($P = 0.0173$, odds ratio = 4.05)

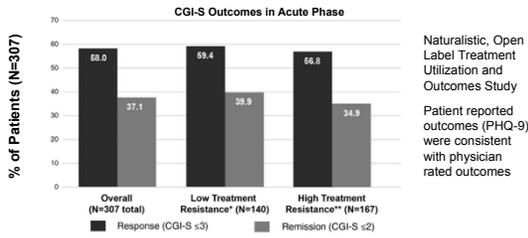
O'Reardon, et al. (2007) *Biological Psychiatry*; George, et al. (2010) *Arch Gen Psychiatry*

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Consistent Response and Remission Rates Across a Broad Range of Treatment Resistance

1 in 2 Patients Respond, 1 in 3 Patients Achieve Remission



Naturalistic, Open Label Treatment Utilization and Outcomes Study
Patient reported outcomes (PHQ-9) were consistent with physician rated outcomes

LOCF Analysis of intent-to-treat population

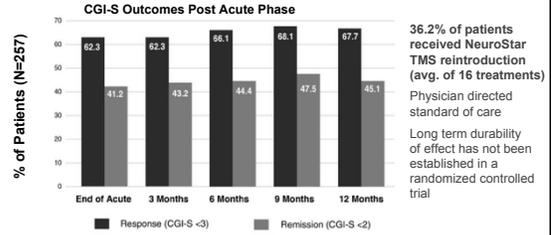
*0-1 adequate antidepressant medications; **2 adequate antidepressant medications
Carpenter, et al. (2012), Depression and Anxiety

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NeuroStar is the Only TMS System with Proven Durability Measured Over 12 Months

68% of study population in response, 45% in remission



36.2% of patients received NeuroStar TMS reintroduction (avg. of 16 treatments)
Physician directed standard of care
Long term durability of effect has not been established in a randomized controlled trial

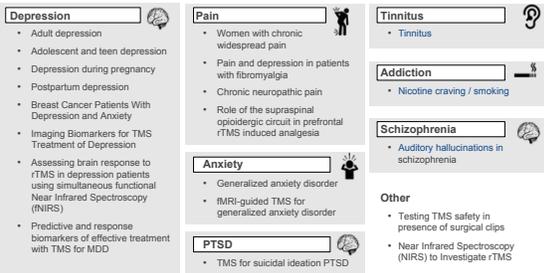
LOCF Analysis of intent-to-treat population

Neuronetics, Data on file, NCT 00104611

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Areas of Ongoing Research in Investigator-Initiated Studies



Limited to investigational use in these areas. Investigators are responsible for ensuring clinical protocols have been reviewed by an Institutional Review Board and meet applicable regulatory requirements for investigational use.

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TMS Therapy: Real World Outcomes

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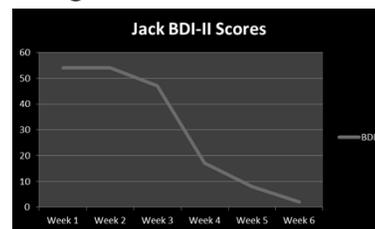
Case Study: Jack

Jack is a 60-year-old male referred by his psychiatrist He has a history of depression that dates back to 1998. He was hospitalized in Fort Collins, Colorado. He has been on medication and in counseling since essentially that time. He is diagnosed with PTSD, Major Depression and possible Bipolar 2 Disorder. Jack suffered sexual abuse and verbal abuse at the hands of his parents and other family members when he was a child. He was initially diagnosed with Major Depression and started on Prozac. This did not work for him. He remembers trying Wellbutrin and Paxil. Wellbutrin was not effective and Paxil gave him serious side effect. Throughout the years he has also been on Effexor, Cymbalta and Seroquel, with minimal to no efficacy. He has been on lithium for the last 13 years and Lamictal for approximately ten years. He took Namenda for about three months several months ago but this was not effective either.

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Jack: Progress over 6 weeks



"I'm not sure how many weeks its been [since I finished] maybe 4, but doing great. I wake up every day and stop and then say, I'm not depressed! I asked my wife if it's a sin to feel this good. Thanks for giving my life back!!!"
- Jack

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Where Can I find Help?

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More than 650 NeuroStar® Locations in the U.S.

Alaska Hawaii

Private Practices Institutions/ Government

Data compiled 07/01/15

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Does Insurance Cover the Cost of TMS?

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230M Covered Lives

As of 7/1/15

- Anthem BCBS
- BCBS of Alabama
- BCBS of Arizona
- BCBS of Florida
- BCBS of Kansas
- BCBS of Kansas City
- BCBS of Louisiana
- BCBS of Massachusetts
- BCBS of Michigan
- BCBS of Minnesota
- BCBS of Nebraska
- BCBS of Northeastern PA (NEPA)
- BCBS of Rhode Island
- BCBS of South Carolina
- BCBS of Tennessee
- BCBS Vermont
- Blue Care Network
- Blue Cross of Idaho
- Blue Shield of California
- BMC HealthNet
- Cabela Medicare
- CareFirst Blue Cross
- CommunityCare of Oklahoma
- EmblemHealth
- Fallon Community Health of Massachusetts
- FEHP (Fed Blue)
- First Coast Service Option
- Harvard Pilgrim Health Care
- Hawaii Medical Services Assoc
- HCSC
- Health Net
- Health New England
- Health Now
- Health Plan of Nevada
- Highmark BCBS
- Horizon BCBS of New Jersey
- Humana, Inc.
- Independence Blue Cross
- Kaiser Permanente Oregon
- MVP Health Care
- National Association of Letter Carriers
- Neighborhood Health Plan MA
- Neighborhood Health Plan of Rhode Island
- Rhode Island Medicaid
- NCS (Medicare)
- Novitas Medicare JH
- Novitas Medicare JL
- Optima Behavioral Health
- Optum/United Behavioral Health*
- Palmetto GSA
- Premiera Blue Cross
- Priority Health
- Rocky Mountain Health Plan*
- Tufts Health Plan
- UHC Community Plan (Medicaid of New England)
- UniCare (Massachusetts State Employees)
- Vermont Medicaid
- WA State HCA

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Madison Area Insurance Providers

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CPT® Category I Codes

90867 Therapeutic repetitive transcranial magnetic stimulation treatment; initial, including cortical mapping, motor threshold determination, delivery and management

90868 Subsequent delivery and management, per session

90869 Subsequent MT re-determination with delivery and management

Source: Current Procedural Terminology 2013, American Medical Association
CPT is a Registered Trademark of the American Medical Association

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To schedule an appointment or for more information, contact:

TMS Center of Madison

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608.231.2200

www.connectionsounseling.com

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