Transcranial Magnetic Stimulation (TMS)

- How it works and what it does; evidence and clinical observations

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Robert Olsen MD

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- TMS provider DBA Best Mind Behavioral Health, Oregon
- Education/experience
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  - General surgery residency at Texas Tech UHSC-El Paso 1994-99
  - Psychiatry residency at UNM 2001-4
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  - Private practice 2013-current
- TMS provider since 2017-current

- No other financial disclosures to report

Transcranial Magnetic Stimulation (TMS)

• Transcranial Magnetic Stimulation (TMS) is an important option for treatment resistant depression (TRD)

• Depression sidelines millions of people contributing to morbidity and mortality and lower quality of life measures

• Psychotherapy helps in many cases and sound psychopharmacology results in less than half remission rate. Medications help many millions with major depressive disorder in the US, but they do not help, or are not tolerated, by many others due to prohibitive side effects

• TMS does not work for everyone, but there is outcome data that can predict improved results

• Willingness to change predicts better outcomes in mental and physical health. Addressing medical complications and any other causes of secondary depression or mental fogginess improves outcomes as well

• TMS is specifically designed to stimulate the cerebral cortex affecting the structures involved in mood and mood regulation directly

• TMS is low risk. Most (if not all) NM insurance covers TMS for TRD

Objectives

- How does TMS enact change in symptoms of depression?
- Current indications and outcomes
- Durability of TMS

Pre-test

- What is the incidence of depression yearly?

1. 16,000 people
2. 160,000 people
3. 1,600,000 people
4. 14-16M people

- Transcranial Magnetic Stimulation is not covered by health insurance plans.

1. True
2. False

- Which sentence(s) are true about Transcranial Magnetic Stimulation (TMS)

1. Non-invasive outpatient treatment for major depression
2. TMS outcomes are improved with active lifestyle changes
3. TMS stimulates brain derive neurotropic factor and neuroplasticity
4. TMS is very well tolerated with low drop out rate

Major Depression

- MDD affects more than 16.1 million American adults, or about 6.7% of the US population age 18 and older in a given year
- The leading cause of disability in the U.S. for ages 15 to 44

- Kessler RC, et al JAMA 2003:
- 14 million in US with MDD
- 7.2 million treated
- 4 million poorly served due to inadequate response or intolerance of side effects

Major Depression DSM5

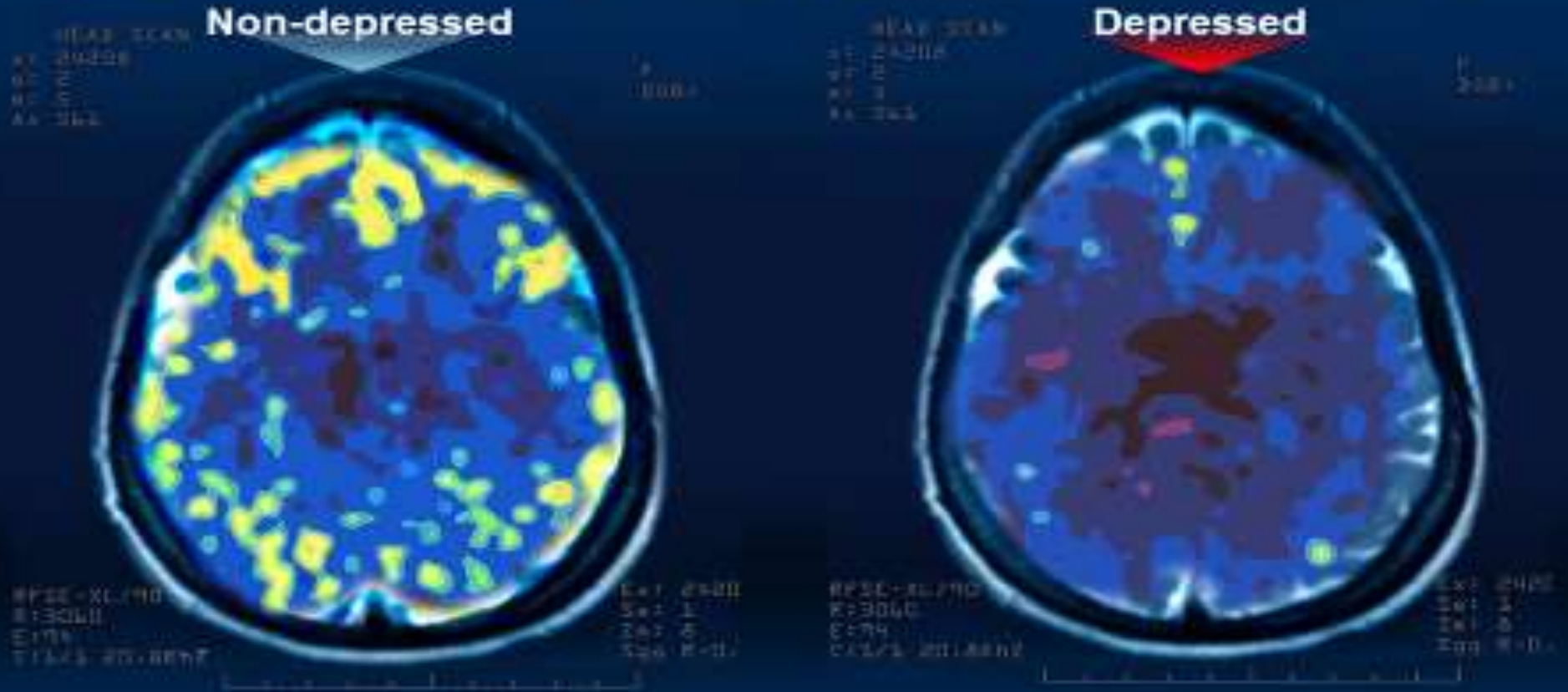
Five or more of the following symptoms during a two-week period, and at least one of those symptoms must be a depressed mood or loss of interest:

- Depressed mood
- Loss of interest or pleasure
- Significant weight loss or gain
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Fatigue or loss of energy

Other criteria for MDD include:

- Symptoms cause significant distress or impairment in social, occupational, or other important areas of functioning
- Episode is not caused by a substance or another medical condition
- Episode is not better explained by another disorder
- No history of manic or hypomanic episode

Brain Activity is Reduced in Depression



A PET Scan measures vital functions such as blood flow, oxygen use and blood sugar (glucose metabolism)

Source: Mark George, M. D. Biological Psychiatry Branch Division of Intramural Research Programs, NIMH 1993

PET Scan in Major Depression

- Hypo-activity:
  - Prefrontal cortex: planning complex cognitive behavior, personality expression, decision making, and moderating social behavior
  - Striatum: voluntary movement coordination
  - Hypothalamus: links to endocrine system
  - Hippocampus: memory
- Hyperactivity: anterior cingulate cortex: for decision making and emotional regulation

Depression Incidence: NIH

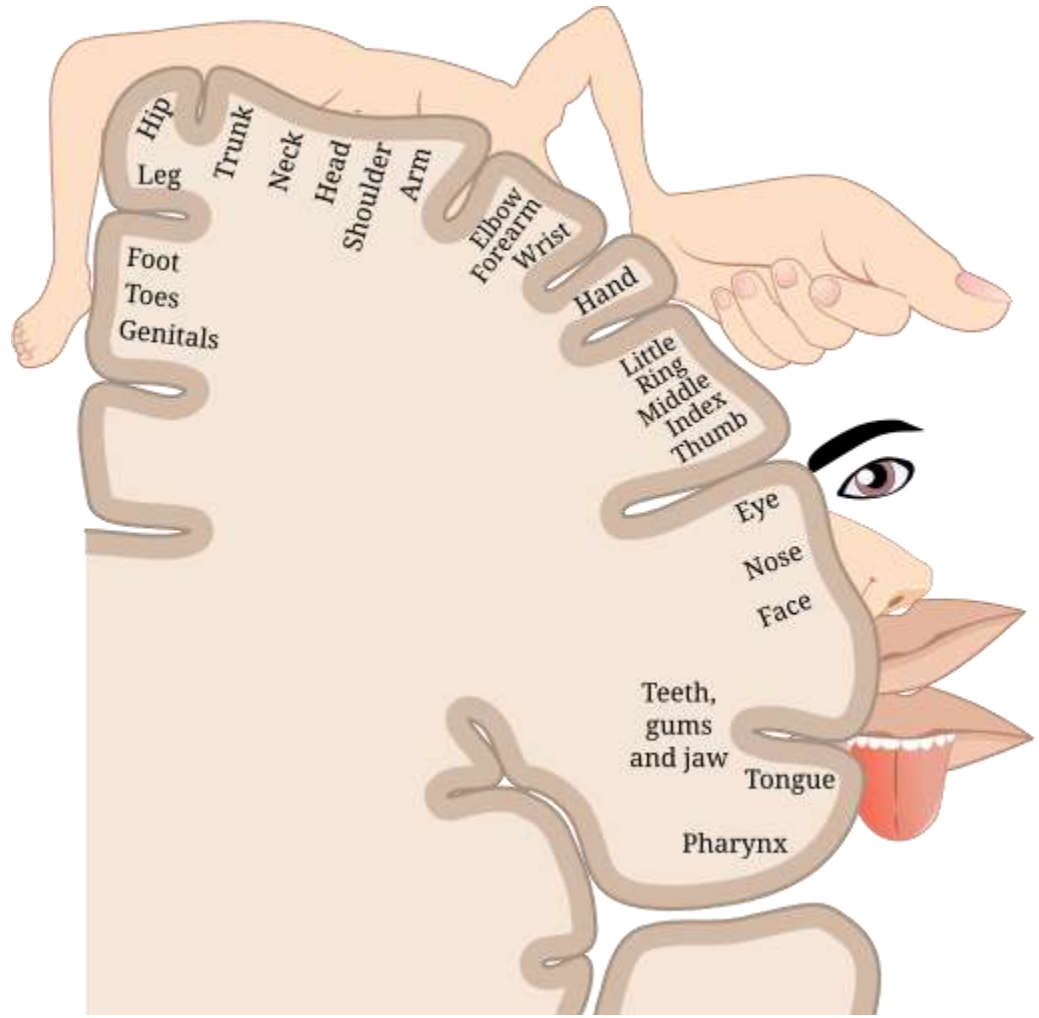
- 2021: 14.5 million U.S. adults (18+) had at least one major depressive episode with severe impairment = 5.7% of all U.S. adults
- **Treatment of Major Depressive Episode Among Adults:** 61.0% U.S. adults with major depressive episode received treatment in the past year
- Among those individuals with major depressive episode with severe impairment, an estimated 74.8% received treatment in the past year
- **Prevalence of Major Depressive Episode Among Adolescents**
  - 5 million adolescents (12-17 y) in US had at least one major depressive episode = 20.1% of the U.S. population aged 12 to 17
  - F>M and highest among **adolescents reporting two or more races (27.2%).**

Antidepressants

- work to change the tone of serotonin, norepinephrine, and dopamine in the brain
- They show positive effects to improve mood, increase concentration, and improve agitation and insomnia
- Effect not limited to the brain: side effects of sexual dysfunction, nausea and GI distress, blurry vision, dry mouth, changes in blood pressure, weight gain, among others
- Remission with medications achieved in 30-40%

What is TMS?

- Based on Faradays' work: an electric current passed through a ferromagnetic wire induces a magnetic field. This idea was developed into a coil that directs the magnetic field into a point
- Magnetic fields penetrates humans and is used in Magnetic Resonance Imaging (MRI) for diagnostic purposes. With MRI, hydrogen atoms in the body are aligned with the magnet, then realign (or flip) when not under the influence of the magnet, resulting in different patterns. This atom flip is interpreted into a visual representation of the anatomy based on tissue density
- With TMS, the magnetic field is directed at the cerebral cortex resulting in brain excitation resulting in improved blood flow, improved metabolism, increase in brain derive growth factor culminating in “neuroplasticity” and improvement in clinical depression and anxiety
- During the development of TMS, when the directed magnetic point is directed on the human motor strip, it stimulates a response in downstream neurons innervated by the particular part of the motor strip (think Homunculus)


Hip
Leg
Trunk
Neck
Head
Shoulder
Arm
Elbow
Forearm
Wrist
Hand
Foot
Toes
Genitals
Little
Ring
Middle
Index
Thumb
Eye
Nose
Face
Teeth,
gums
and jaw
Tongue
Pharynx

What is TMS

- TMS uses most commonly, a figure of 8 coil design which produces a magnetic field cone that penetrates the scalp and excites the underlying cortex
- The brain is highly connects so stimulating the cortex can also impart changes to deeper structures, most notably, limbic structures
- This stimulation promotes increases metabolism and glucose uptake, induces neuroplasticity (new ways to learn) and increase brain derive growth factor, which helps maintain healthy neurons

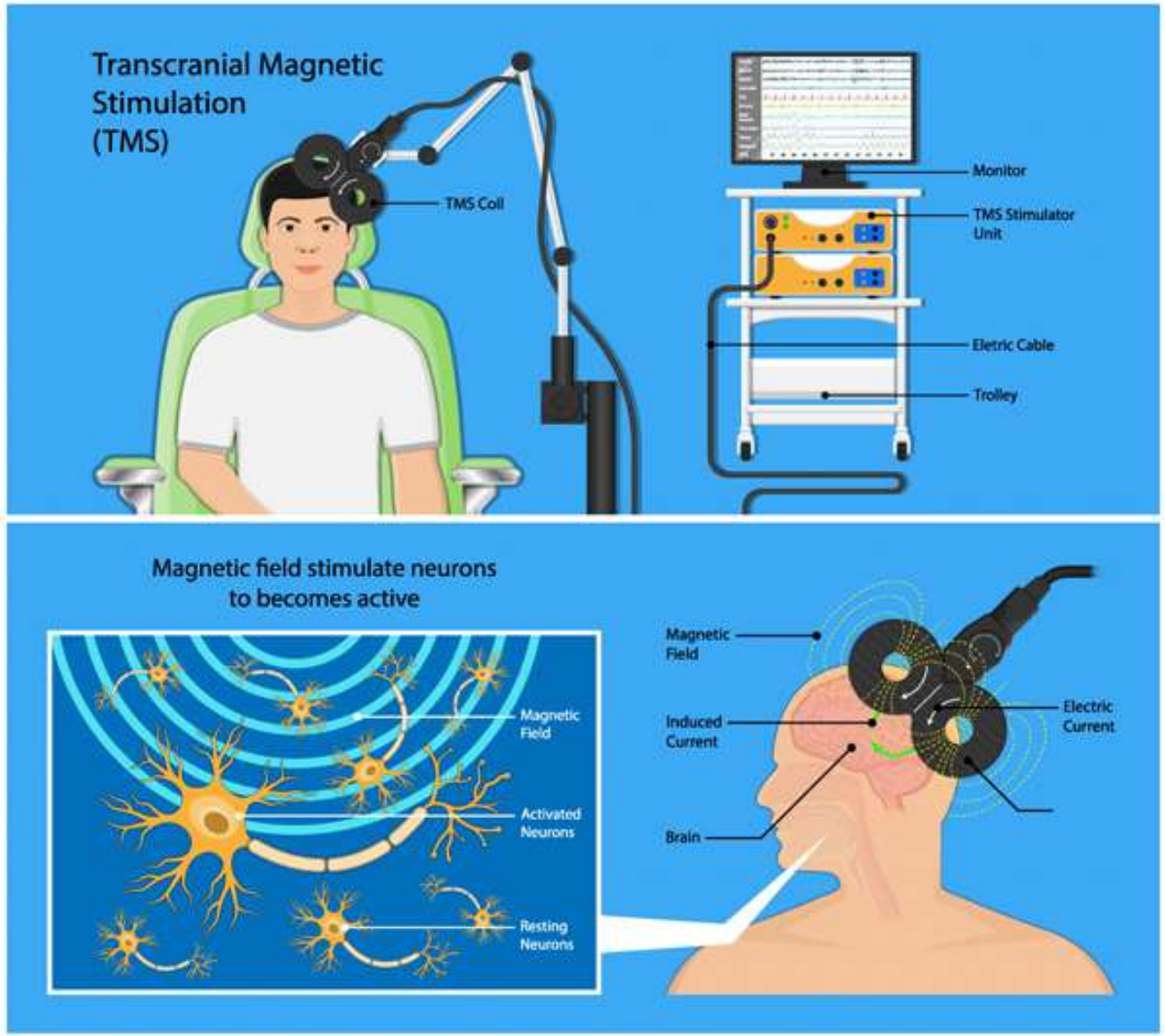
What is TMS

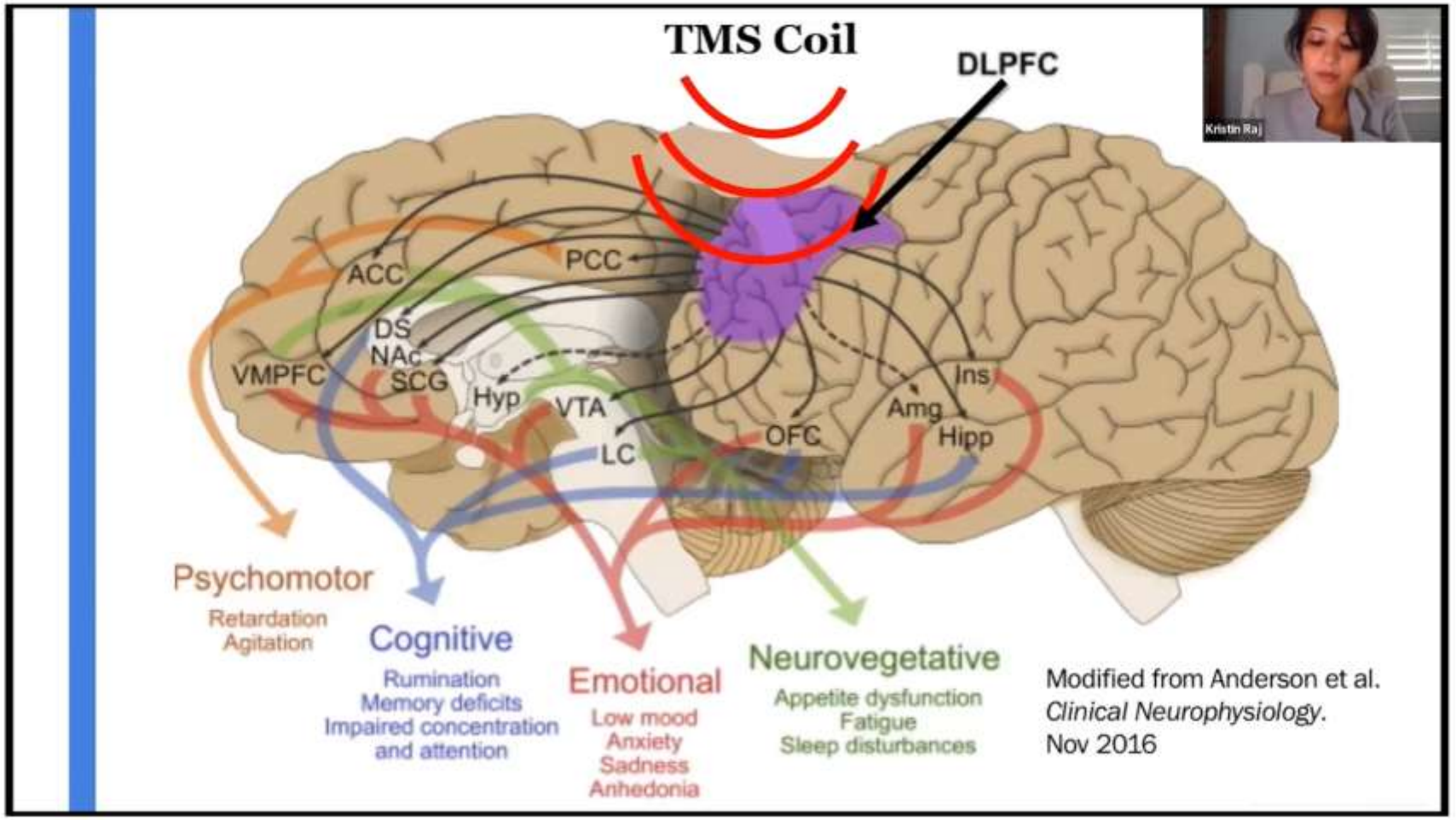
- TMS: an invisible magnetic field in the shape of a cone 2 inches long and 1 inch wide (approx.) is produced when electricity is passed through a figure of 8 coil of ferromagnetic wire. This size of the cone depends on the amount of energy passed through the wire
- This invisible magnetic cone penetrates the skin, bone, and has a direct effect on the brain. The magnetic field excites the area that lies on top of deeper limbic structures

During TMS, a magnetic coil is placed over the patient’s head and delivers brief, repetitive magnetic pulses to the targeted area of the brain

These pulses stimulate nerve cells and can alter brain activity

TMS is typically administered as a series of daily treatments over days to several weeks


Transcranial Magnetic Stimulation (TMS)
TMS Coil
Monitor
TMS Stimulator Unit
Eletric Cable
Trolley
Magnetic field stimulate neurons to becomes active
Magnetic Field
Activated Neurons
Resting Neurons
Magnetic Field
Induced Current
Brain
Electric Current


TMS Coil
DLPFC
ACC
PCC
DS
NAc
VMPFC
SCG
Hyp
VTA
LC
OFC
Amg
Ins
Hipp
Psychomotor
Retardation
Agitation
Cognitive
Rumination
Memory deficits
Impaired concentration
and attention
Emotional
Low mood
Anxiety
Sadness
Anhedonia
Neurovegetative
Appetite dysfunction
Fatigue
Sleep disturbances
Modified from Anderson et al.
Clinical Neurophysiology.
Nov 2016
Kristin Raj

Brain Anatomy

- Amygdala
  - seat of anxiety becomes small with chronic stress and trauma
  - “fluffs out” when treated with tms and antidepressants
- Hypothalamus
  - relay station for the brain
  - All central nervous system wiring goes through this and all thoughts are informed by the deep emotional centers

TMS Mechanism of Action

- The most widely accepted mechanism for the long-term neural effects of rTMS (repetitive TMS) is that rTMS can alter synaptic plasticity, mainly the long-term potentiation/depression (LTP/LTD) of excitatory synaptic transmission
- Pharmacological and animal studies have shown that rTMS affects the neural processes that are related to the initiation and maintenance of synaptic plasticity, including the gene and protein expression underlying N-methyl-D-aspartate (NMDA) receptor function
- One of the earliest attempts to use TMS for treatment concerned major depression (George et al., 1995, Pascual-Leone et al., 1996).

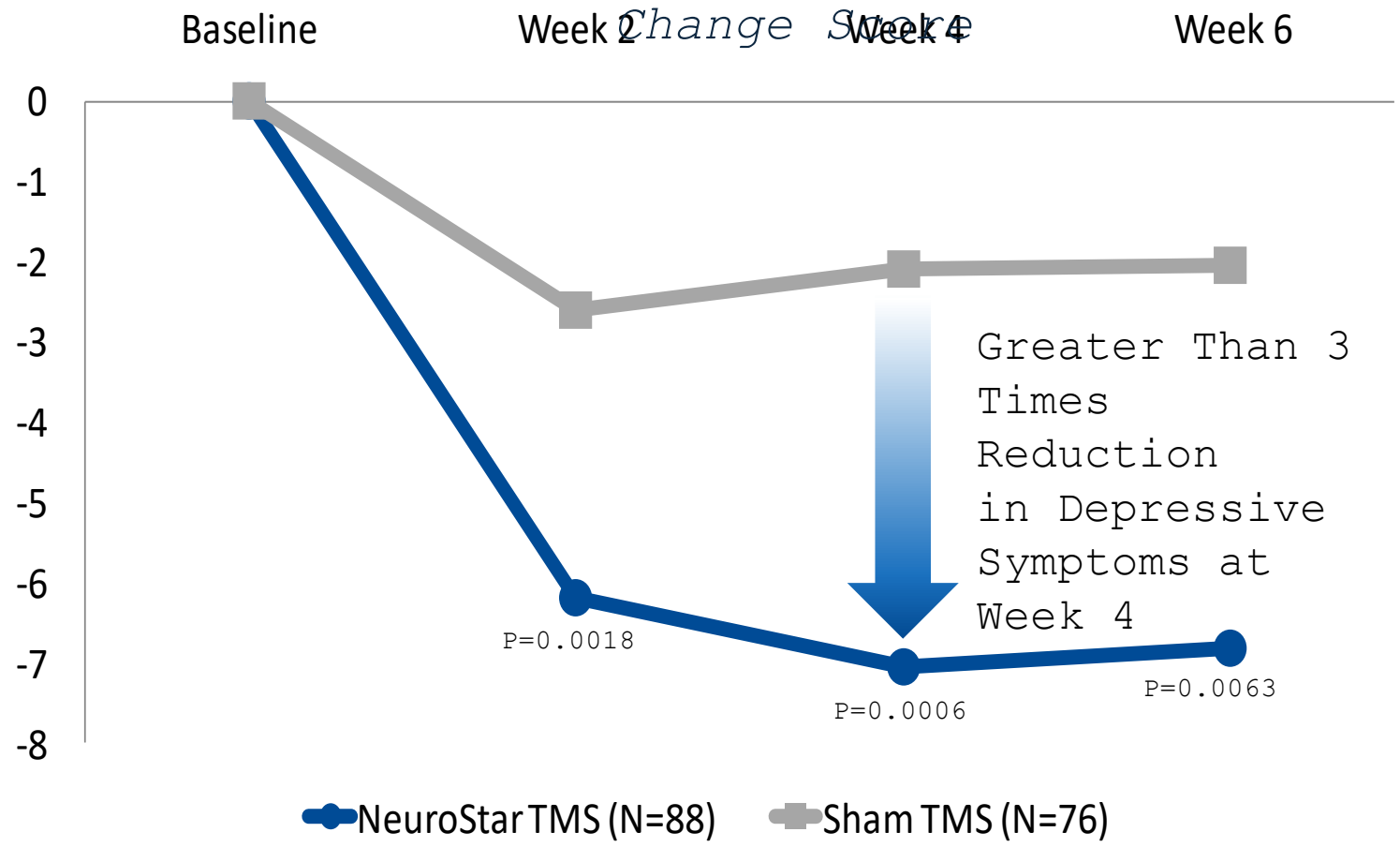
TMS Mechanism of Action

- Induces new connections (neuroplasticity), which allows for new ways of thinking: feed these connections with good information and thoughts
- Increases brain derived growth factor which heals neurons; increased gray matter volume and hippocampus improvements
- Changes circulation and metabolism increases in the area with stimulation
- Changes in neuroamines which mediate mood and anxiety: improved serotonergic, GABA, and glutamine levels

NMDA receptor function

- Controls synaptic plasticity
- Involved with learning and memory
- Involved with pain processing in CNS on dendrites, dendritic spines and in the spinal dorsal horn (receive and process sensory information from the body)
- Too much: excitotoxic: thought to be involved with Alzheimer’s
- Located throughout CNS and peripheral nervous system, in the heart and GI endothelial cells

Randomized Controlled Trial Key Outcome Measure – MADRS Change Score



LOCF Analysis of intent-to-treat population

Demitrack and Thase (2009), *Psychopharm Bulletin*

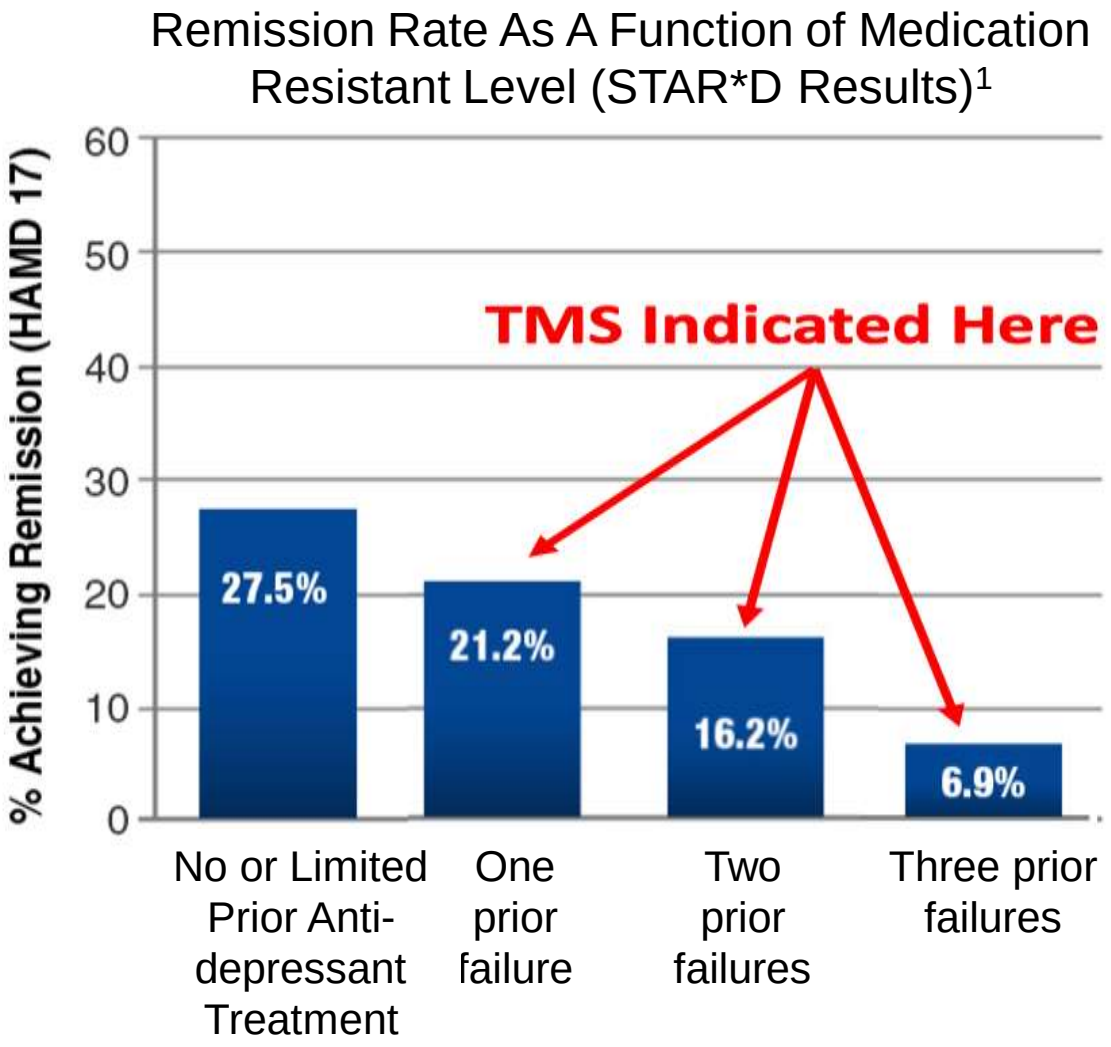
TMS Safety Profile

- TMS is a non-invasive procedure that uses magnetic pulses t stimulate specific areas of the brain
- FDA approved for treatment of major depressive disorder, severe
- Well tolerated and minimal side effects: discomfort at treatment site, headache, infinitesimally rare seizures
- Contraindications: seizure disorder, history of neurosurgical conditions like aneurysms, or intracranial implants, cochlear ear implants

APA 2010: following the failure of initial treatment, “acute phase treatment may include pharmacotherapy, psychotherapy, the combination of medication and psychotherapy, or somatic therapies such as ECT, TMS, or light therapy…”

TMS is covered by insurance companies with a prior approval process highlighting the treatment history including medication doses, durations and effects of medication trials, and the use of psychotherapy in the current episode

TMS vs. Antidepressant Medication



- No systemic side effects - insomnia, fatigue, blurred vision, GI distress, sexual dysfunction, dry mouth, tremor, autonomic instability, etc. (as with medications)
- No known cognitive side effects
- Noninvasive - No need for sedation, anesthesia, hospitalization, or recovery time (as with ECT, DBS, VNS)
- Effective in treatment resistant depression (TRD) where medications can have diminishing returns[1,2,3,4]

[1]Avery et al. (2008) *J Clin Psych*
[2] Carpenter et al. (2012) Depress Anxiety
[3] Connolly et al. (2012) *J Clin Psych*
[4] Fava et al. (2006) *Am J Psychiatry*
[5] Trivedi et al. (2006) *Am J Psychiatry*

TMS Indications: FDA cleared

- In adults 18+ for MDD, severe, that has failed to respond to 2+ antidepressant medication trials from at least 2 different classes, with or without anxious features
- In OCD that has failed to respond to evidenced-based medication trials from at least 2 different classes AND a trial of evidenced-based psychotherapy (ERP)
- In smoking cessation, for patients who have failed to respond to standard medications and behavioral interventions (Brainsway)
- For patients with multiple sensitivities or contraindications to medications
- For patients who have responded to a prior course of TMS; decline ECT
- Age 15-17: one medication failure for major depressive disorder (Neurostar)

Improve TMS Outcomes

- Stay on your current antidepressant dose: many people want to stop medications, but all modalities working together result in increased rates of remission. The time to consider eliminating medications for mood, is after remission has been achieved x 6+ months.
- Minimize engaging in negative input right after treatment. These treatments induce neuroplasticity, so feed your healing brain better messaging: mental health apps, calm music, etc. for at least 30-60 minutes after treatment
- Sleep hygiene
- Daily exercise of any form: this not only helps the body, but helps the brain stay active
- Mental health options: Mastery of Love by Miguel Ruiz, Evolving Self Confidence by Terry Dixon, Mindapps.org, others
- Regular psychotherapy: cognitive behavioral therapy, interpersonal therapy, and/or dialectical behavioral therapy
- Engage with healthy people
- No alcohol, hard drugs, or cannabis

Improve TMS Outcomes

- Verbiage for clients:
- Avoid toxicity: be it situations, bad habits, or people. This includes TV and media
- Work on negative self-talk. We can be our own worst enemy and self references often are negative (“stupid,” “loser,”, “why did I say that?” etc., etc.). While doing treatment, adopt a new way to refer to yourself that is positive (“sweetie”) or at least neutral to help retrain your brain. TMS causes neuroplasticity: your brain is working out, so give it something worthwhile to incorporate
- Your one commodity is your attention. Companies pay a lot of money to get it, and people make all sorts of efforts to get your attention, so empower yourself and realize that you matter. Only you can decide where to give your attention, so give your attention to life-affirming and loving situations and people

Improve TMS Outcomes

Personalized Targeting of Brain Regions:

a. Individualized mapping based on measurements (F3) which corresponds to the left dorsolateral prefrontal cortex (DLPFC)
b. Neuroimaging Guidance: Using functional MRI (fMRI) or EEG to guide TMS placement can help target networks associated with the disorder, ensuring the correct brain regions are stimulated: this has yet to be validated, though is promising

Optimal Stimulation Parameters: Frequency Adjustment

a. High frequency for depression, lower frequency in anxiety
b. Stimulation Intensity: motor threshold (minimum intensity that induces a motor response): 80-120% MT for treatment

Combination with Other Therapies:

a. Cognitive Behavioral Therapy (CBT): no improved outcomes with CBT while getting TMS, but better outcomes with concurrent psychotherapy during TMS treatment course and afterwards
b. Tai Chi before each TMS session improves outcomes
c. Pharmacotherapy: in combination with medications leads to better outcomes, especially in treatment-resistant patients

Improve TMS Outcomes

Customized Treatment Duration

a. Extended or Booster Sessions: Some are early responders and others are delayed responders: tradition is 36 session: some respond by treatment #20, others by treatment #50
b. “Maintenance” Sessions: nice concept but not fully defined

Patient-Specific Factors

a. Patient age and condition (such as brain lesions or neurodegenerative diseases) can affect TMS outcomes
b. Ensuring the patient is mentally prepared and engaged in their treatment can lead to better responses. Supportive environments and managing expectations can enhance the placebo effect and overall outcomes.

Neurofeedback: Combining TMS with neurofeedback may enhance TMS effects by helping patients self-regulate their brain states

Improve TMS Outcomes

Boosting Neuroplasticity: adjunct therapies such as aerobic exercise, cognitive training

D-cyclosterine (antibiotic that treats TB) binds and activates NMDA receptors in the brain and spinal cord: with adjunct rx, increased response and remission

Optimizing Timing and Scheduling: once daily or accelerated

Monitoring and Adapting Treatment: biomarkers or adjusting treatment parameters

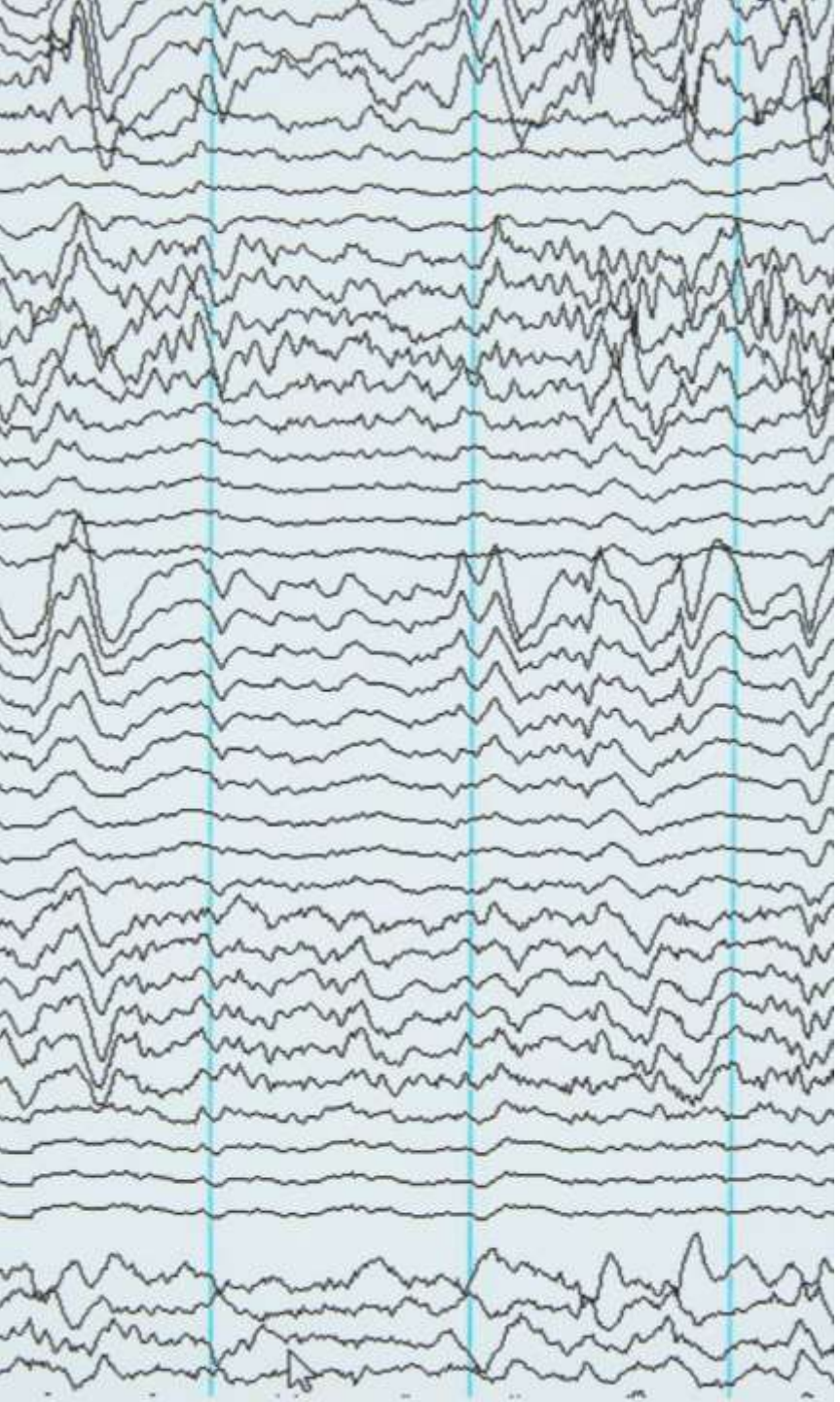
- Moderate depression
- Symptoms are more severe than mild depression and are beginning to change a person's life.

- Severe depression
- Symptoms are most severe and significantly impact a person's life, including their job, career, and relationships.

STAR*D: 2800 Patients

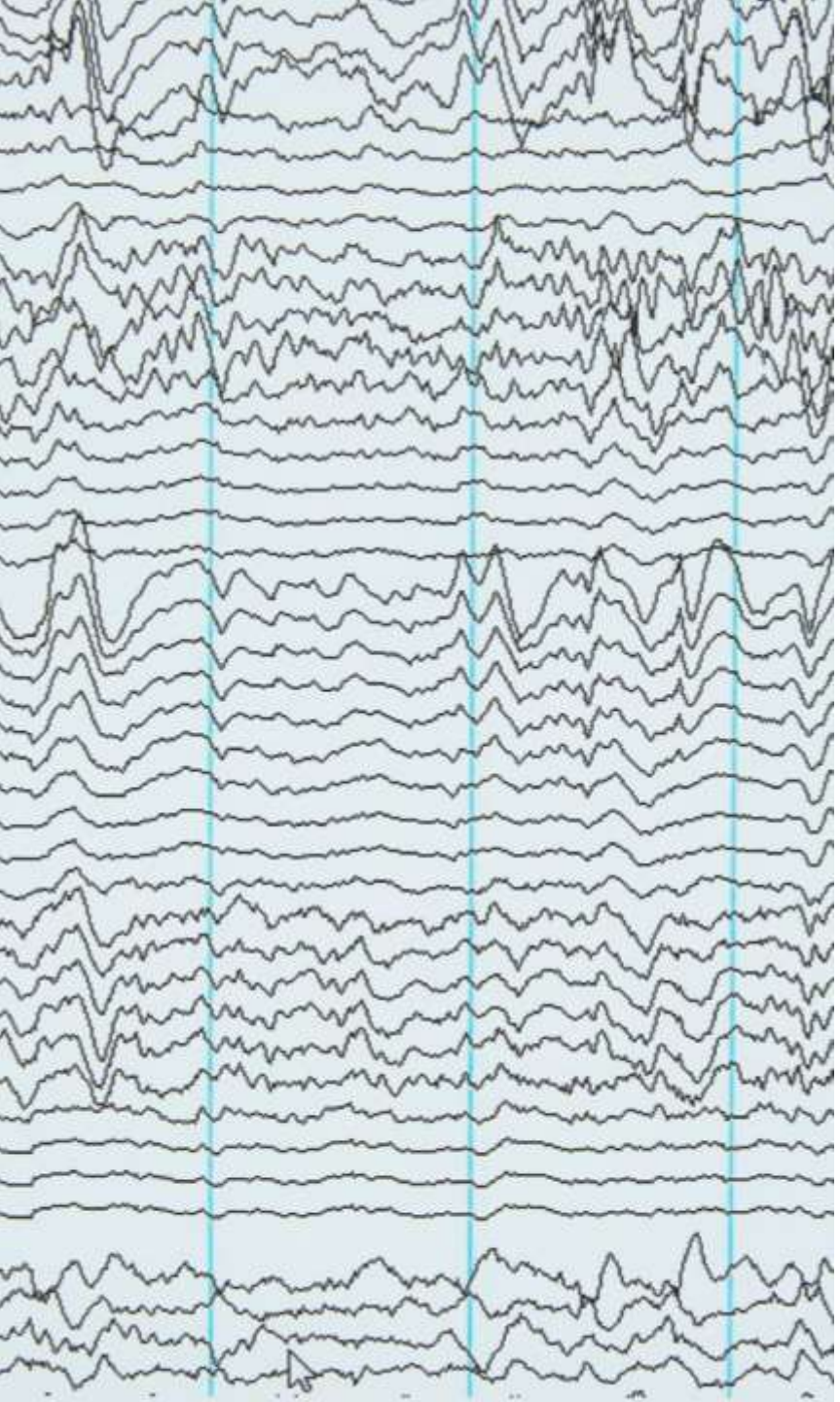
- Level 1: citalopram
- Level 2: augment with buspirone or bupropion
- Level 2: switch to venlafaxine or bupropion or sertraline
- Level 3: augment with T3 or lithium
- Level 3: switch to nortriptyline or mirtazapine
- Level 4: switch to venlafaxine AND mirtazapine or tranylcypromine

- Sequenced Treatment Alternative to Relieve Depression: Control Clin Trials 2004 Feb;25(1):119-42; PMID 15061154



STAR*D

- STAR*D shows that the likelihood of achieving remission is limited and declines with each successive treatment attempt
- First line treatment: 27% achieve remission (HAM-D 17)
- One prior treatment failure: 21%
- Two prior treatment failures: 16%
- Three prior treatment failures: 7%



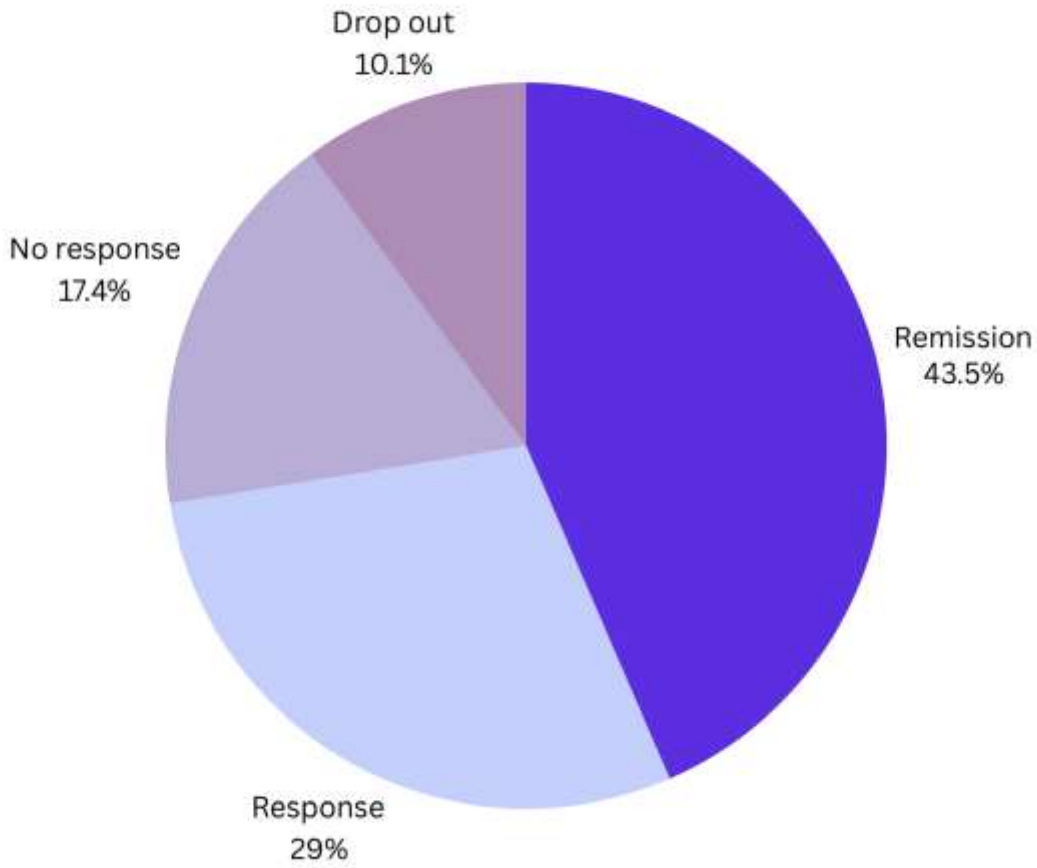
STAR*D

- Likelihood of discontinuing treatment increased with successive medication attempt
- First line treatment effect: 9% stop medication due to side effect
- One prior treatment failure: 23%
- Two prior treatment failures: 35%

Remission rates for MDD with RX versus ECT

- **SSRIs**: Remission rates are usually between 20% and 39%
- **TCAs**: Remission rates are usually between 46% and 53%
- **Reboxetine**: Remission rates are usually around 42%
- **Antidepressants**: Remission rates are usually between 30% and 40%
- Clinical trials often report higher remission rates than effectiveness studies, which include more representative samples of patients
- Combining cognitive therapy (CT) with antidepressant medication (ADM) can increase response rates by 6% to 33%
- ADM is the most common treatment for depression, especially for more severe cases. However, half of patients who achieve remission with ADM will relapse before fully recovering
- Electroconvulsive therapy (ECT) has a reported remission rate of 70–90% for severe depression

Sunrise TMS outcomes 2021-5



TMS	Date Range	1/1/2023	to	9/23/2024

Response

Total

Total	Response	Remission
232	142	71
	61.21%	30.60%

Patient Retention

Completed		232	Completed	85.61%
Discontinued (Internal Conflict)		13	External Conflict	9.59%
Discontinued (External Conflict)		25	Internal Conflict	4.80%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		1		

Clackamas

Total	Response	Remission
73	52	29
	71.23%	39.73%

Completed		73	Completed	93.59%
Discontinued (Internal Conflict)		2	External Conflict	3.85%
Discontinued (External Conflict)		3	Internal Conflict	2.56%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		0		

Tigard

Total	Response	Remission
48	27	10
	56.25%	20.83%

Completed		48	Completed	78.69%
Discontinued (Internal Conflict)		5	External Conflict	13.11%
Discontinued (External Conflict)		8	Internal Conflict	8.20%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		0		

Salem

Total	Response	Remission

Completed		20	Completed	83.33%

Spravato | 1/1/2023 | to | 9/23/2024

Response

Total

Total	Response	Remission
72	45	22
	62.50%	30.56%

Clackamas

Total	Response	Remission
21	16	7
	76.19%	33.33%

Tigard

Total	Response	Remission
25	15	10
	60.00%	40.00%

Salem

Total	Response	Remission
0	0	0
	#DIV/0!	#DIV/0!

Patient Retention

Total

Completed		72	Completed	61.54%
Discontinued (Internal Conflict)		8	External Conflict	31.62%
Discontinued (External Conflict)		37	Internal Conflict	6.84%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		0		

Clackamas

Completed		21	Completed	67.74%
Discontinued (Internal Conflict)		0	External Conflict	32.26%
Discontinued (External Conflict)		10	Internal Conflict	0.00%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		0		

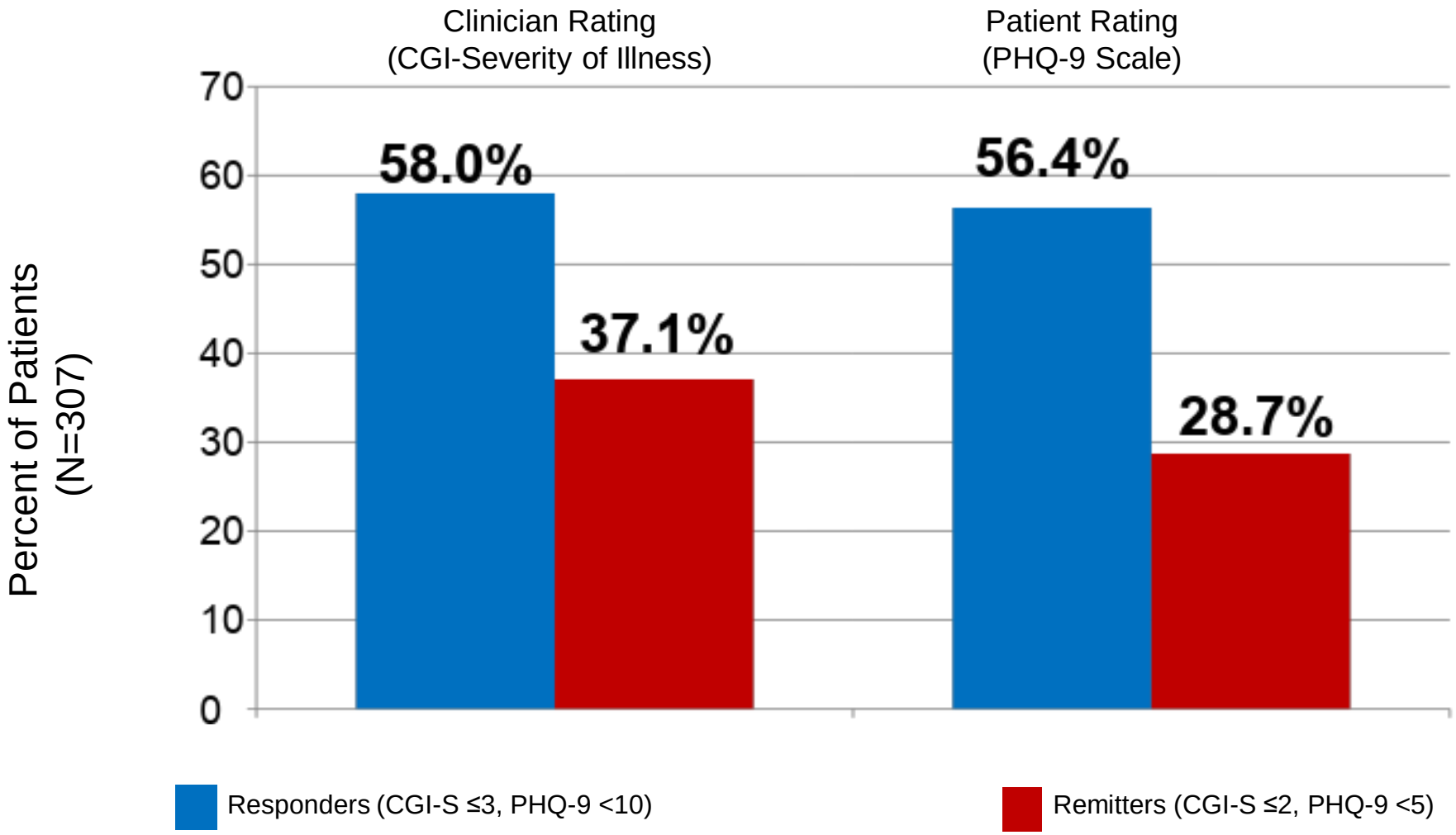
Tigard

Completed		25	Completed	58.14%
Discontinued (Internal Conflict)		3	External Conflict	34.88%
Discontinued (External Conflict)		15	Internal Conflict	6.98%
NoStart (Internal Conflict)		0		
NoStart (External Conflict)		0		

Salem

Completed		0	Completed	#DIV/0!
Discontinued (Internal Conflict)		0	External Conflict	#DIV/0!
Discontinued (External Conflict)		0	Internal Conflict	#DIV/0!

Remission from Depression is possible with TMS Therapy:



LOCF Analysis of intent-to-treat population

- **1 in 2 Patients Respond**
- **1 in 3 Patients Achieve Remission**

Carpenter et al. (2012) *Depression and Anxiety*

Depression Protocol

- 3000 pulses per session 10 Hz left lateral prefrontal cortex x 36+/- sessions at 18-20 minutes per session
- Later responders often require up to 60 sessions
- Late responders can improve with more pulses per session (4000-5000)
- Majority of anxiety symptoms are improved with depression treatment alone
- SAINT protocol: 10 sessions of 3000 pulses per day x 3 days
- Theta burst: triplet of pulses: reduces treatment time to 3 minutes per treatment

Durability of TMS

- Studies have shown that a significant portion of patients who respond to TMS maintain their improvement for at least several months after treatment ends
- One study found that the majority of patients who benefited from active TMS for a major depressive episode maintained this benefit over 24 weeks while on maintenance antidepressant monotherapy
- The durability of TMS treatment means that its effects can persist, potentially reducing the need for continuous treatment
- Clinically seeing 6+ months and effects can continue to improve over that time. Some come back in 6-12 months, others years later, some never need it again

OCD

- Improvements have been made in our understanding and treatment of OCD
- The discovery and use of serotonin reuptake inhibitors (SRIs), especially the selective serotonin reuptake inhibitors (SSRIs), has dramatically improved patient outcome. Between 40–60% of OCD patients given an adequate trial of a SSRIs experience a response to treatment
- Effective behavioral treatment involving cognitive-behavior therapy (CBT) with exposure and response prevention is well established and has improved outcomes

TMS for OCD

- TMS uses magnetic pulses to stimulate the brain, increasing inhibitory activity
- This inhibitory effect helps to modulate hyperactive regions of the brain linked to OCD symptoms
- TMS can reduce the frequency and intensity of obsessions and compulsions

- FDA cleared
- TMS pulses directed at midline frontal area targeting prefrontal cortex, dorsomedial prefrontal cortex, pre-supplementary motor area, anterior cingulate cortex

medications for depression and anxiety for children

- Fluoxetine (ages 8+)
- Escitalopram (ages 12+)

- TMS: age 15+ (studies show safe as young as 9 y)

TMS research & off-label uses

- **ADHD**
- **Anxiety disorders:** Panic attacks, generalized anxiety disorder
- **Substance use disorders:** Addiction to drugs or alcohol
- **Schizophrenia:** Management of hallucinations and cognitive symptoms
- **Autism spectrum disorder:** Potential for improvement in social interaction and communication
- **Migraines and chronic pain:** Reducing the frequency and severity of headaches
- **Post-stroke rehabilitation:** Improving motor function after a stroke
- **Alzheimer's disease and dementia:** Potential to slow cognitive decline

Anxiety Protocol

- 500-800 pulses at 1Hz to right DLPFC (approx. 8 minutes)
- 10-20 sessions
- No research showing it improves outcomes
- It is easier, so better tolerated

TMS and PTSD

- Most recent meta-analyses of TMS for PTSD included 11 randomized controlled trials (RCTs)
- Demonstrated a significant reduction in core PTSD symptoms with a large and medium effect size
- High- and low-frequency TMS, respectively, applied to the right dorsolateral prefrontal cortex (DLPFC)
- Tricare reimburses for PTSD indication: NEW

Other TMS considerations

- Theta burst: sessions 3 months rather than 18 minutes
- Mimics brains natural theta waves
- SAINT: Stanford Accelerated Intelligent Neuromodulation Therapy: 10 sessions per day over 5 days

TMS is FDA cleared for:

- Treatment resistant MDD in adult patients[1] (7 devices cleared)
  - No satisfactory improvement from (or sensitivity/allergy to) 1, or more, antidepressant medications at or above the minimal effective dose & duration in the current episode of depression. Despite this indication, insurers can require 2-4+ med trials, +/- trial of evidence-based psychotherapy
- Treatment resistant Obsessive Compulsive Disorder (OCD), in adult patients [2,3] (2 devices cleared)
- Migraines with aura[4] (single pulse TMS, 1 device cleared)
- Smoking cessation[5] (1 device cleared)

Indications with Promising Data: Level A/B evidence[7]

- Neuropathic Pain[6]
- Post-Stroke[7]
- PTSD[7]
- Fibromyalgia[7]

[1]McIntyre R et al. J Clinical Psychiatry, 2017
[2] Press Release from FDA August 17, 2018
[3]Press Release from FDA August 11, 2020
[4]Lan et al. J Headache Pain, 2017
[5]Press Release from FDA August 24, 2020
[6]Hamid P, et al. 2019
[7]Lefaucheur, JP et al. 2020

Post-test

- What is the incidence of depression yearly?

1. 16,000 people
2. 160,000 people
3. 1,600,000 people
4. 14-16M people

- Transcranial Magnetic Stimulation is not covered by health insurance plans.

1. True
2. False

- Which sentence(s) are true about Transcranial Magnetic Stimulation (TMS)

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4. TMS is very well tolerated with low drop out rate

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