

Interventional Psychiatry: A practical introduction to modern ECT, rTMS, and ketamine antidepressant therapy for established psychiatric providers

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Disclosures

- Dr. Kitay receives funding from Janssen Pharmaceuticals for the conduct of clinical trials involving esketamine administered through Yale University.
- Dr. Kitay has also received honoraria from Janssen Pharmaceuticals.
- This presentation will include discussion of off-label use of ketamine.

Program Objectives

- Define “Interventional Psychiatry” (IP) and understand its role in current clinical psychiatric practice. Participants will be able to describe the attributes of an "Interventional Psychiatry Service (IPS)" that may be adapted to various settings of clinical psychiatric care.
- Understand the fundamental mechanistic and technical aspects of electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS) therapy, and ketamine antidepressant therapy. Participants will become familiar with the current evidence base regarding therapeutic efficacy and the risk/benefit profile for each treatment modality towards understanding appropriate indications for referral.
- Describe practical clinical aspects of IP treatments including: pre-procedure counseling/work-up, elements of safe and effective procedure administration, post-procedure evaluation, and the role of the “outpatient psychiatrist” during various phases of treatment.
- Discuss the role of outpatient psychiatrists in mitigating stigma around- and enhancing access to- IP treatments.

Program Objectives

Through completion of this course, participants will understand how to incorporate these modalities into their treatment planning and develop skills towards:

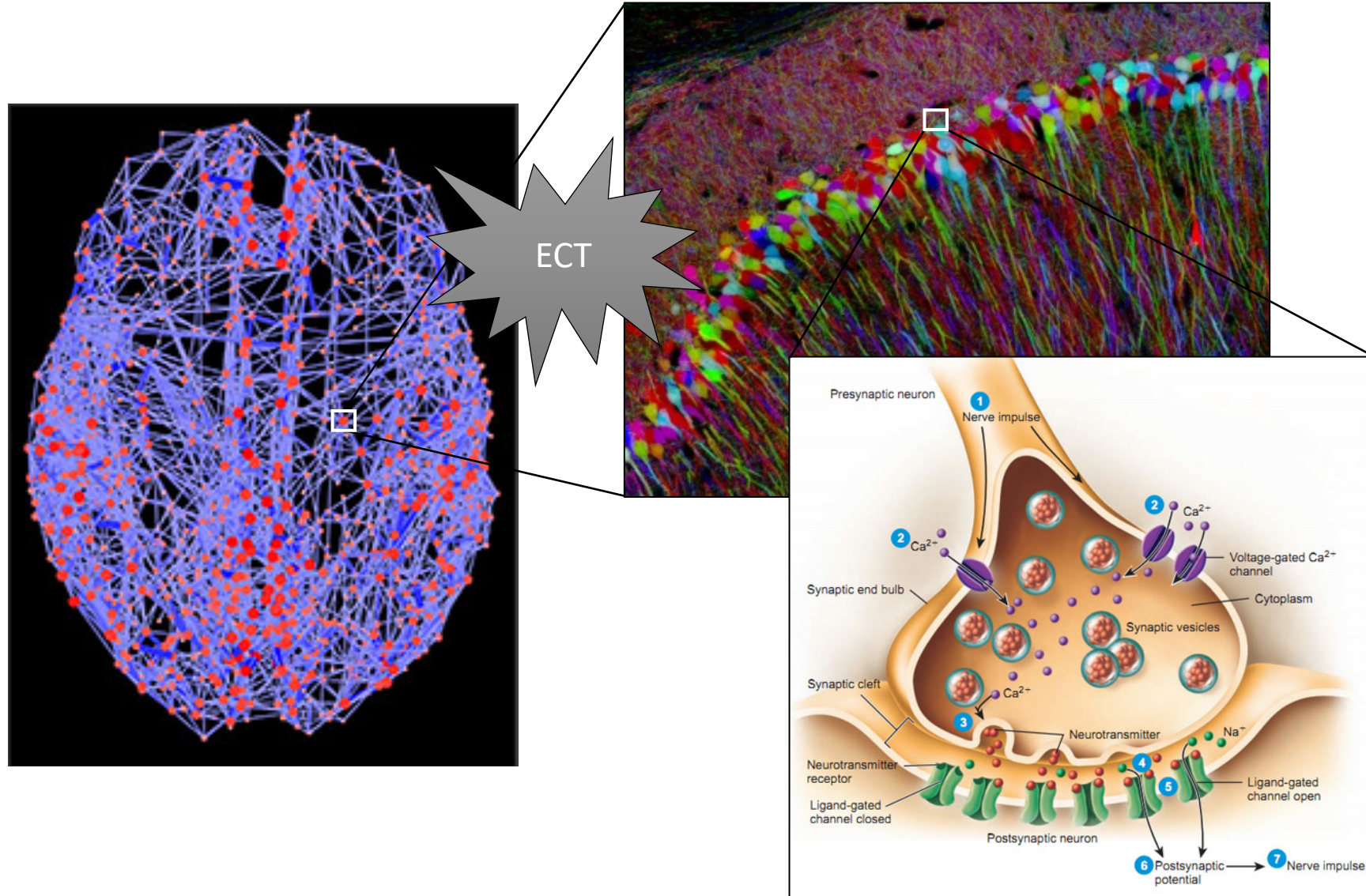
1. Formulating appropriate referrals
2. Providing both accurate and effective pre-treatment counseling in anticipation of referral
3. Acknowledging and discussing stigma towards enhancing openness to referral

Repetitive transcranial magnetic stimulation (rTMS) therapy

Outline:

- Understanding rTMS: from biophysics to network neuroscience
- Understanding the rTMS candidate
 - Evidence for use in MDD/TRD and prognostic indicators of response
 - Evidence for use in OCD
- Understanding the procedure
 - Goals of the procedure
 - A typical treatment course
 - Treatment day
 - Anticipatory side-effects
- Role of the outpatient psychiatrist
 - Practical considerations and formulating candidacy
 - Preparing the patient for consultation/referral
 - Remaining the “primary treater” through an rTMS course

The brain is a complex, *electrochemical network*



Electrode lead placement in ECT – Pseudo-target specificity?

Adapted from Lee WH et al, *NeuroImage*, 2012

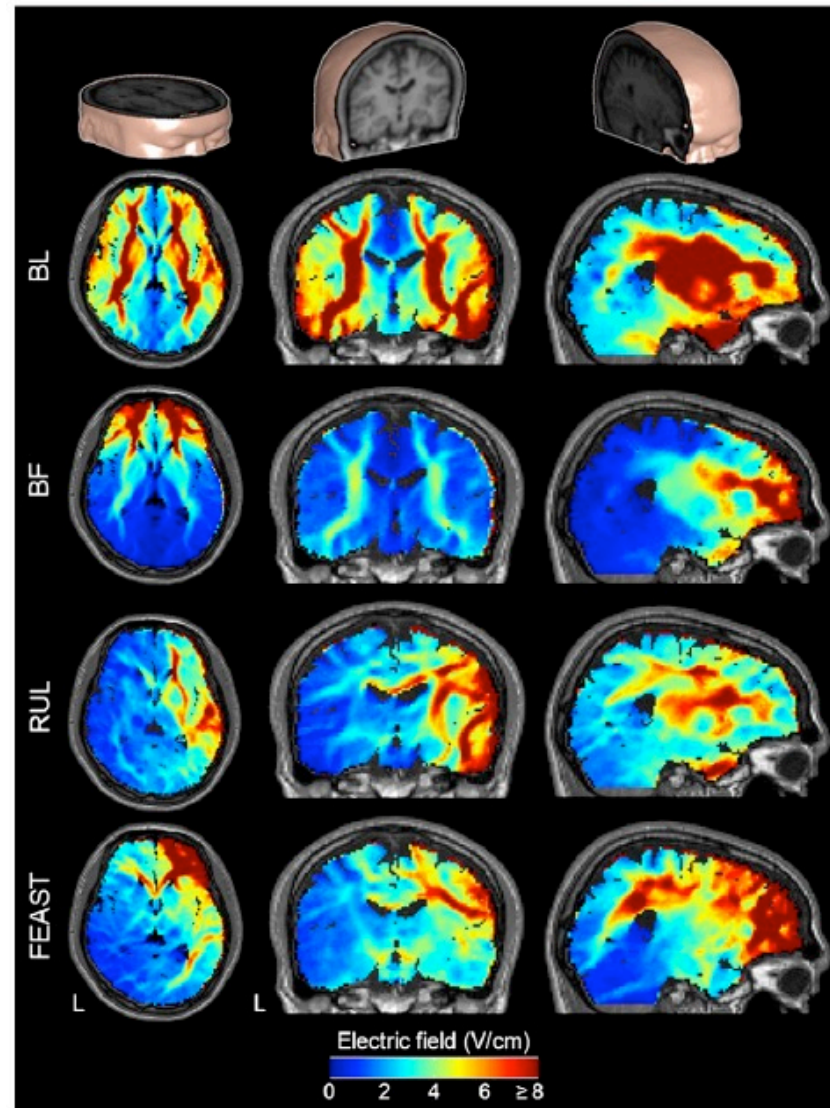
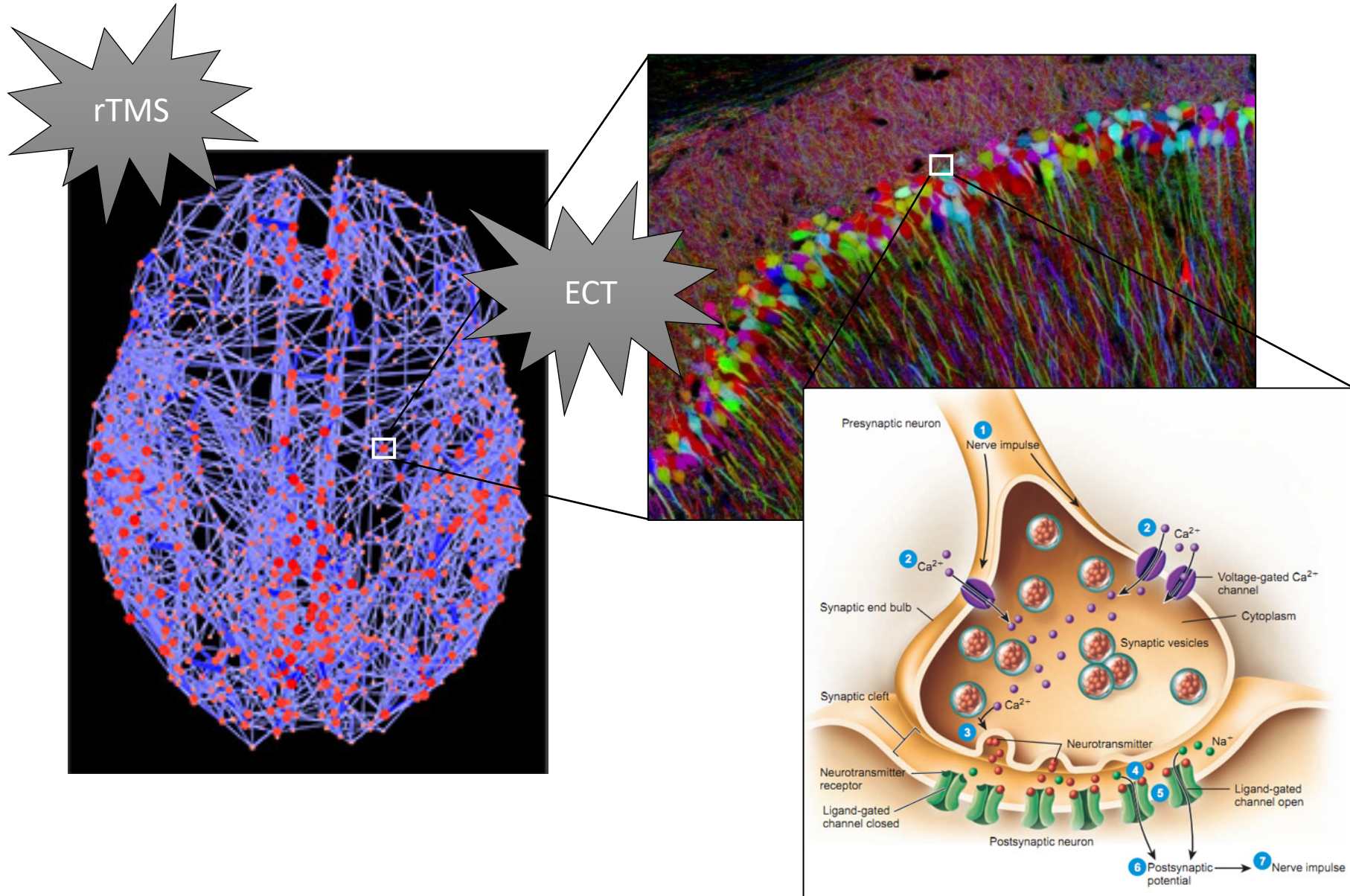
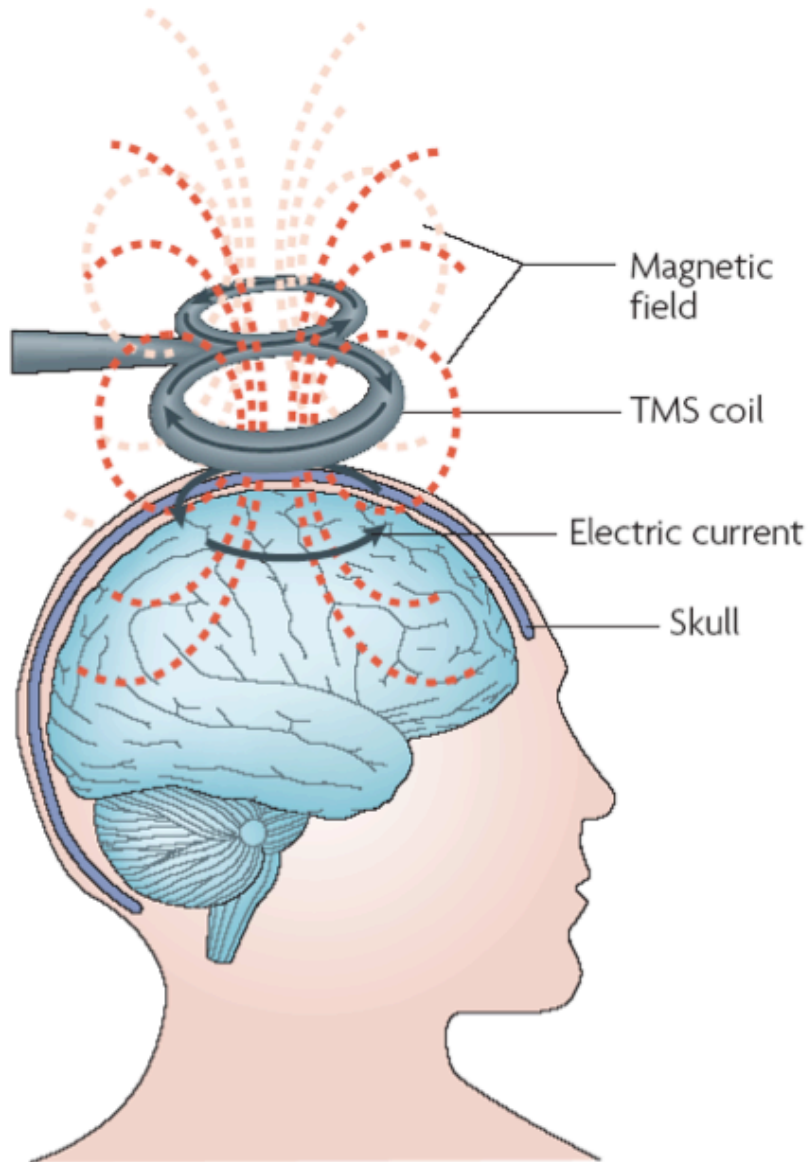


Fig. 3. Cut-away 3D rendering of the head model (top row) and the E-field magnitude spatial distribution in the anisotropic head model for BL, BF, RUL, and FEAST electrode configurations (second to bottom rows, respectively) with 800 mA current. Columns from left to right show axial, coronal, and sagittal views, respectively. The color map is clamped at an upper limit of 8 V/cm for good visibility of the electric field distribution. L: left.

The brain is a complex, *electrochemical network*



rTMS: What is it and how does it work?



- Alternating current passed through a closed loop generates a pulsating magnetic field (Ampere's Law).
- The alternating magnetic field, *capable of penetrating the skull*, generates Eddy current (Faraday's Law) that can influence cortical electrophysiology.
- High frequency (HF) pulses ACTIVATE neurons, while low frequency (LF) INHIBIT neurons.
- Repetitive stimulation leads to changes in neurotransmitters, long term potentiation (LTP), receptor concentration, and epigenetics that can facilitate long-term changes in local plasticity.

rTMS: What is it and how does it work?

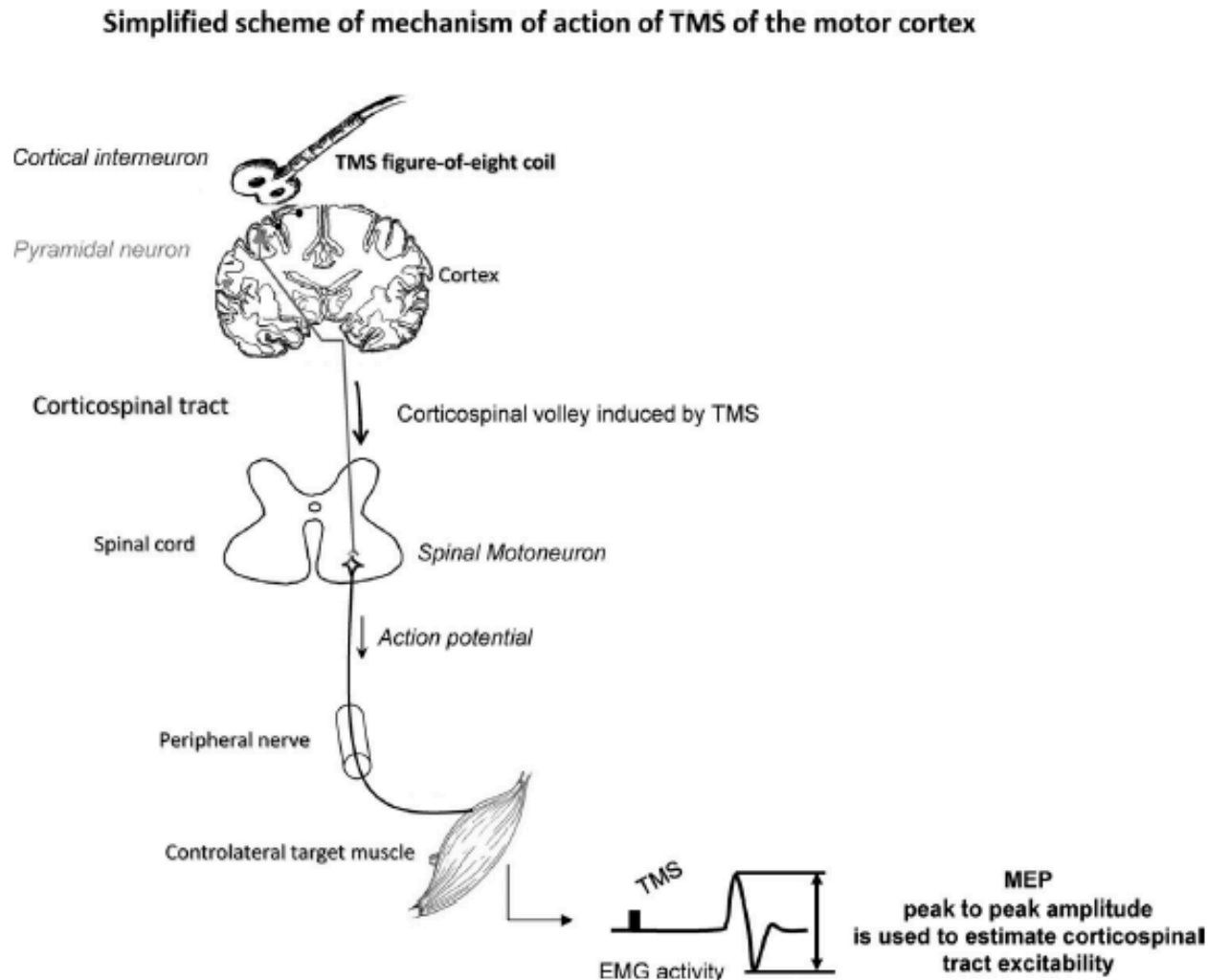
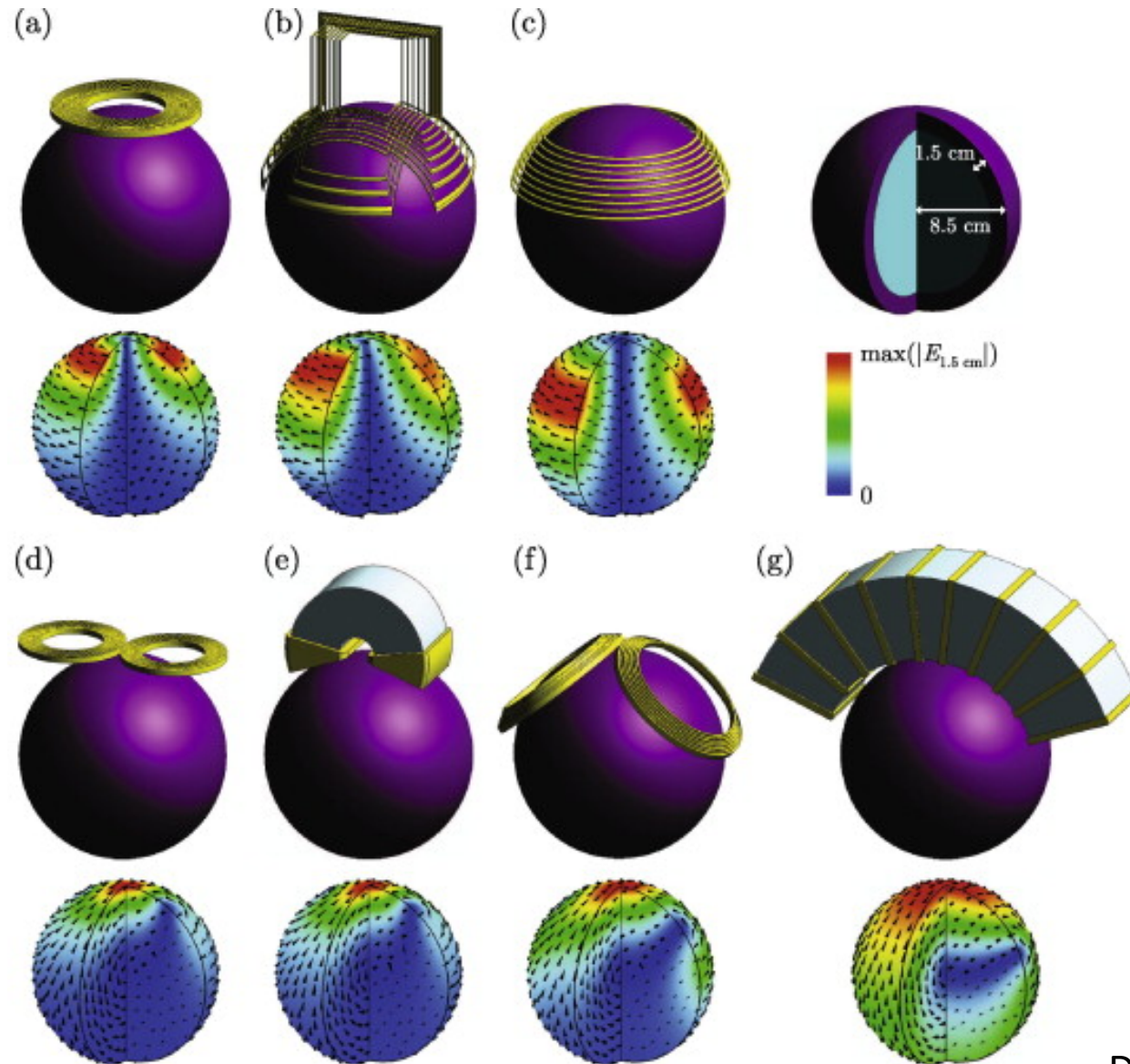


Fig. 1. Transcranial magnetic stimulation (TMS) applied over the motor cortex preferentially activates interneurons oriented in a plane parallel to the brain surface. This placement leads to a transynaptic activation of pyramidal cells evoking descending volleys in the pyramidal axons projecting on spinal motoneurons, also termed the corticospinal tract. Motoneuron activation in response to corticospinal volleys induced by TMS leads to a contraction in the target muscle evoking a motor-evoked potential (MEP) on electromyography (EMG) recorded by using surface electrodes applied over the muscle belly. Its peak-to-peak amplitude is used to estimate excitability of the corticospinal tract.

rTMS: Coil geometry influences field of stimulation



Motivation, Evidence

CONVERGING evidence of dysfunction of the prefrontal cortex in depression. In a study of magnetic stimulation of the surface of the brain, 10 subjects received prefrontal rTMS and 10 subjects received sham rTMS. Six highly medicated subjects were included. Depression scores significantly improved as a whole (Hamilton Depression Rating Scale: 23.8 ± 4.2 (s.d.) at baseline, 19.8 ± 3.03 , 5DF, $p = 0.001$). Subjects showed no side effects. Depression occurred progressively in 3 subjects. In one subject, depression occurred for the first time in 3 months. rTMS appears to be safe, effective for depression.

Several lines of evidence indicate that the left prefrontal cortex is dysfunctional in depression.¹

Most functional neuroimaging studies of depressed subjects have found decreased left prefrontal activity, often in proportion to the rated severity of depression. Additionally, some studies have found that patients with left prefrontal strokes have an increased risk of developing depression. Finally, left unilateral electroconvulsive therapy (ECT) is more effective than right. Recently the technology of transcranial magnetic stimulation (TMS) has been developed and refined, providing the ability to stimulate superficial neurons of the cerebral cortex safely and subconvulsively. The ability to repeat quickly the magnetic stimulus (repetitive TMS; rTMS), has opened up yet another dimension of cortical activation and inhibition. In motor cortex, rTMS has different properties and neurobiological effects to those of single pulse TMS, perhaps because of the ability to stimulate during a neuron's refractory period.² Initially used to study motor function, rTMS has now been used to

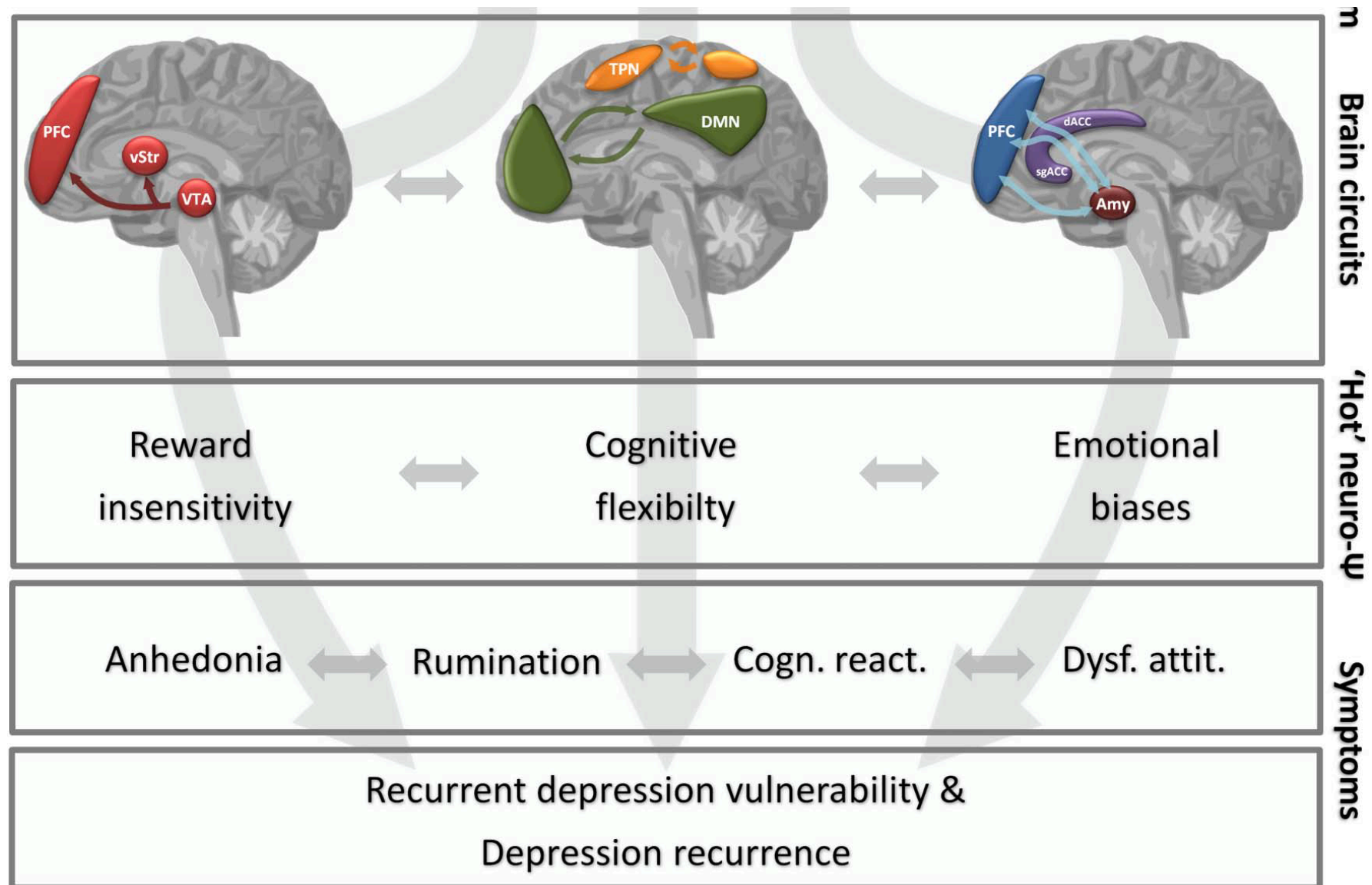
Journal of *neuroreport*

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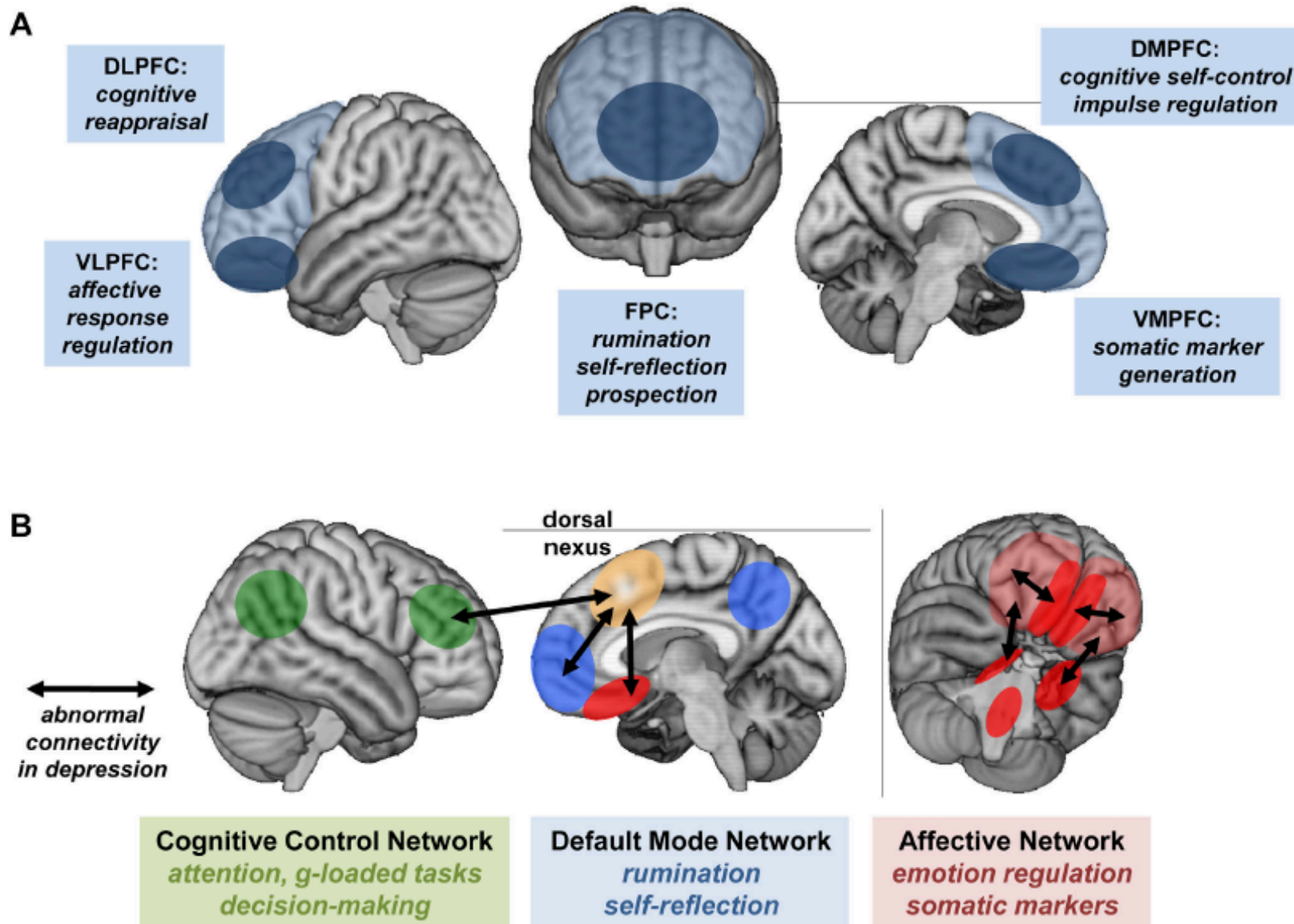
Magnetic
Stimulation
(MS)
in

Ann Callahan,¹
Peter Basser,⁵
Robert M. Post¹

Cortico-limbic dysfunction in depression



Cortico-limbic dysfunction in depression



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

John P. O'Reardon, H. Brent Solvason, Philip G. Janicak, Shirlene Sampson, Keith E. Isenberg, Ziad Nahas, William M. McDonald, David Avery, Paul B. Fitzgerald, Colleen Loo, Mark A. Demitrack, Mark S. George, and Harold A. Sackeim

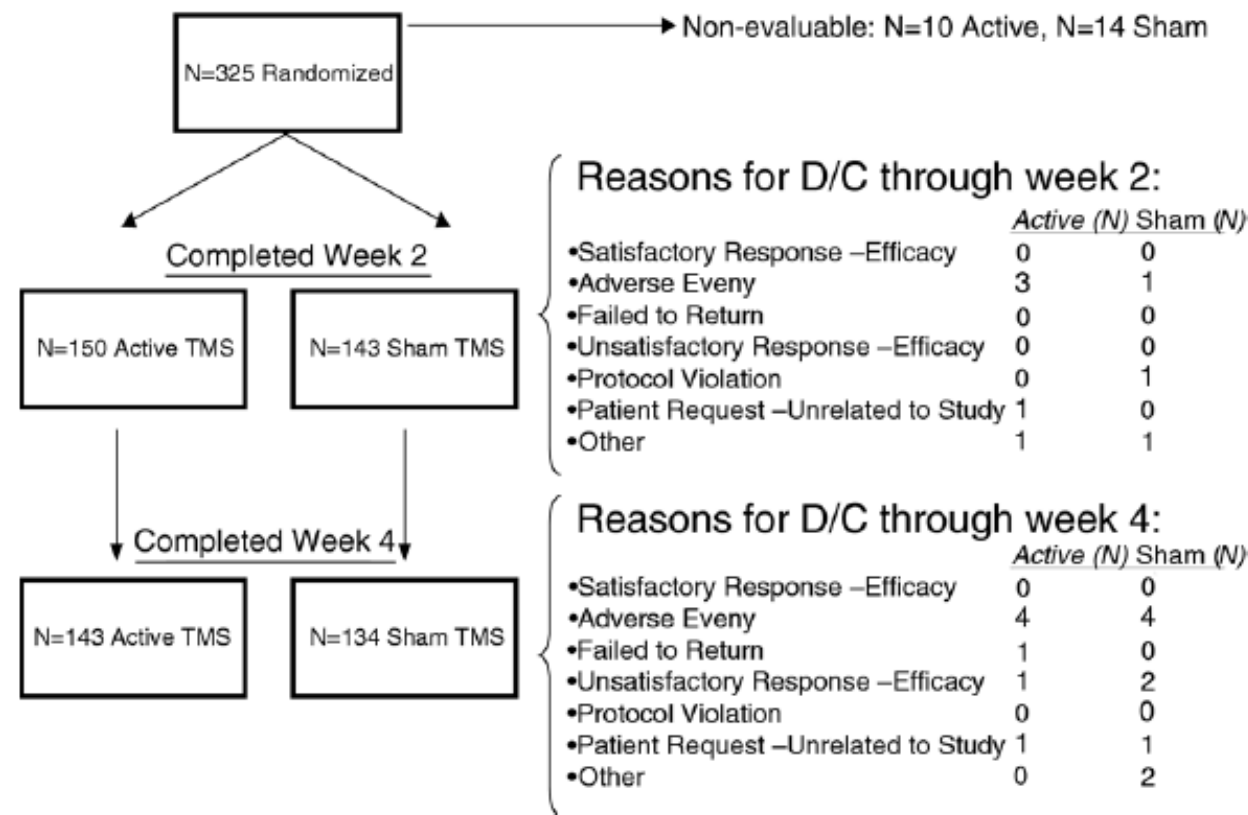


Table 3. Adverse Events Occurring in the Active Treatment Group at a Rate of 5% or More and at Least Twice the Rate for Sham (with ME-Coded Preferred Terms Shown)

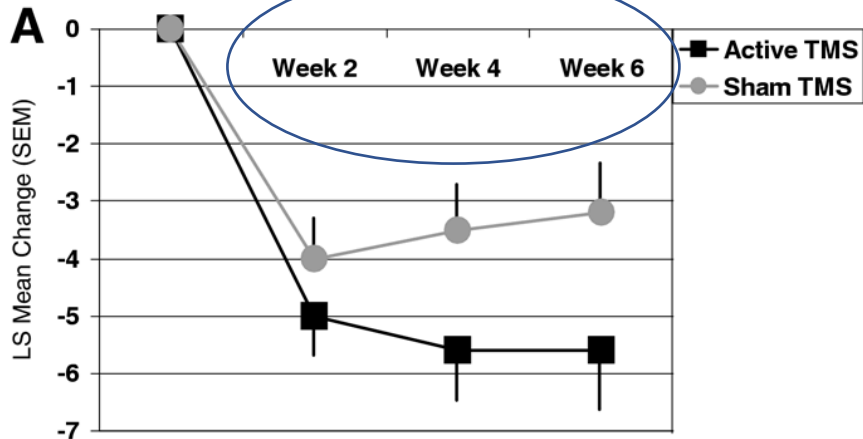
Body System Preferred term	Active TMS (n = 165) n (%)	Sham TMS (n = 158) n (%)
Eye disorders		
Eye pain	10 (6.1)	3 (1.9)
Gastrointestinal Disorders Toothache	12 (7.3)	1 (.6)
General Disorders and Site Administration Conditions		
Application site discomfort	18 (10.9)	2 (1.3)
Application site pain	59 (35.8)	6 (3.8)
Facial pain	11 (6.7)	5 (3.2)
Musculoskeletal and connective tissue disorders		
Muscle twitching	34 (20.6)	5 (3.2)
Skin and subcutaneous tissue disorders		
Pain of skin	14 (8.5)	1 (.6)

MedDRA, Medical Dictionary for Regulatory Activities.

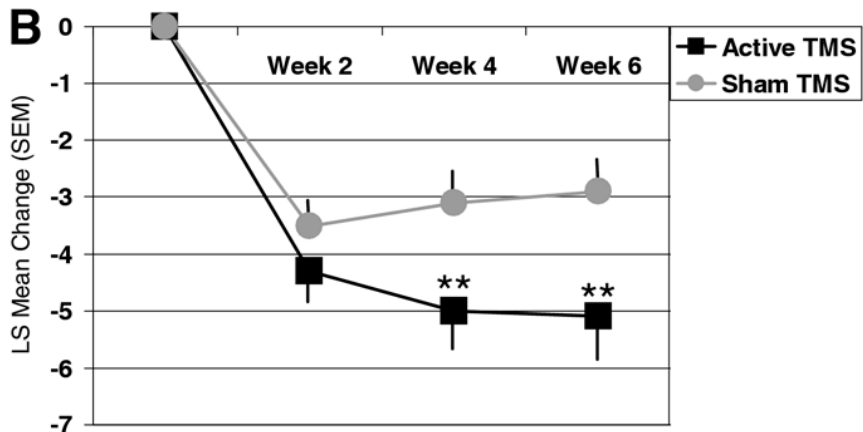
Figure 1. Reasons for study discontinuation through the primary efficacy time point (week 4).

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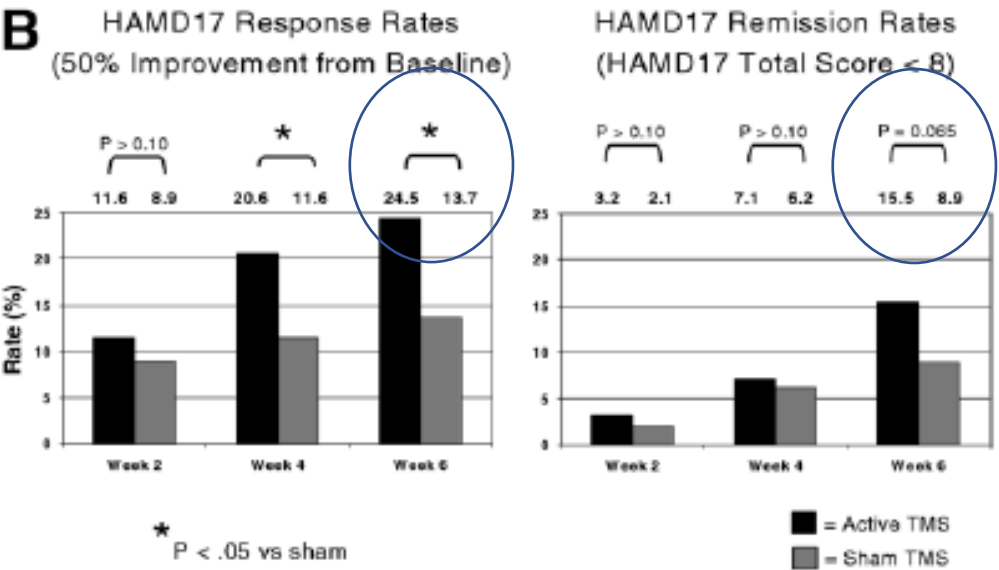
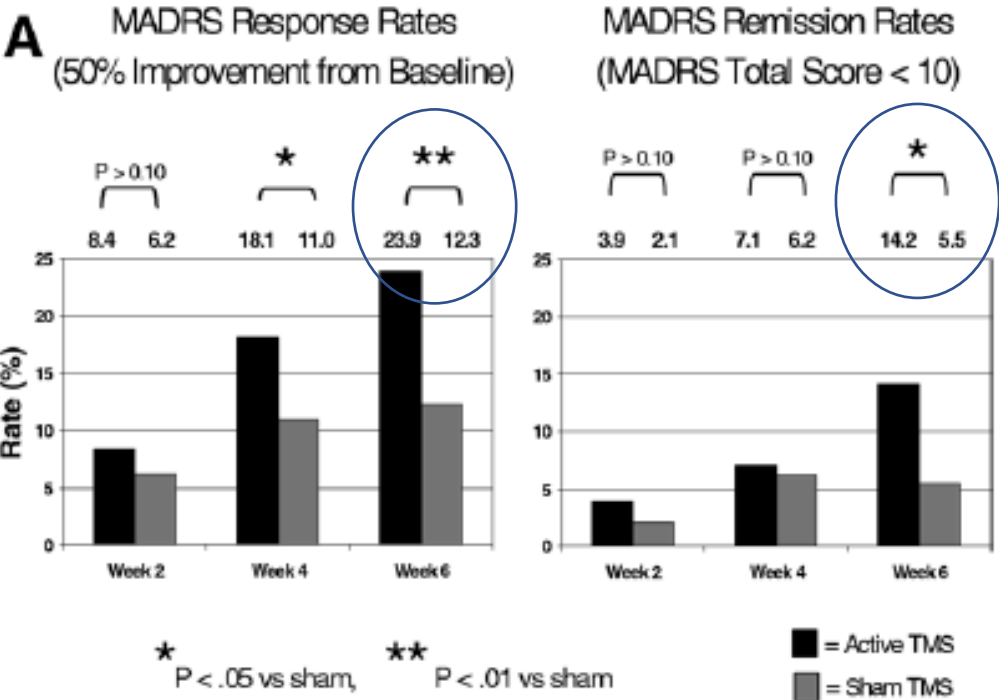
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($p=0.057$ for week 4 contrast, $p=0.058$ for week 6 contrast)



** $P < 0.01$
($p=0.006$ for week 4 contrast, $p=0.005$ for week 6 contrast)



Research Article

TRANSCRANIAL MAGNETIC STIMULATION (TMS) FOR MAJOR DEPRESSION: A MULTISITE, NATURALISTIC, OBSERVATIONAL STUDY OF ACUTE TREATMENT OUTCOMES IN CLINICAL PRACTICE

Linda L. Carpenter, M.D.,^{1*} Philip G. Janicak, M.D.,² Scott T. Aaronson, M.D.,³ Terrence Boyadjis, M.D.,⁴ David G. Brock, M.D.,⁵ Ian A. Cook, M.D.,⁶ David L. Dunner, M.D., FACP⁷, Karl Lanocha, M.D.,⁸ H. Brent Solvason, Ph.D., M.D.,⁹ and Mark A. Demitrack, M.D.⁵

TABLE 1. Demographic and clinical characteristics of study population (N = 307)

Demographic variables	
N (%) females	205 (66.8)
Age (years, mean \pm SD)	48.6 \pm 14.2
Age range	18 – 90
Disease history	
Recurrent illness course, N (%)	285 (92.8)
Comorbid anxiety disorder, N (%)	46 (15.0)
History of inpatient hospitalization for depression, N (%)	134 (43.6)
History of prior treatment with ECT, N (%)	16 (5.2)
Antidepressant treatment history	
Number of overall antidepressant treatment attempts in current illness episode, mean (SD)	3.6 (3.1)
(Range)	(0 – 21)
Number of dose/duration adequate antidepressant treatments in current episode, mean (SD)	2.5 (2.4)
(Range)	(0 – 14)
Baseline symptom scores	
CGI-Severity, mean (SD)	5.1 (0.9)
IDS-SR total score, mean (SD)	45.7 (11.0)
PHQ-9 total score, mean (SD)	18.3 (5.2)

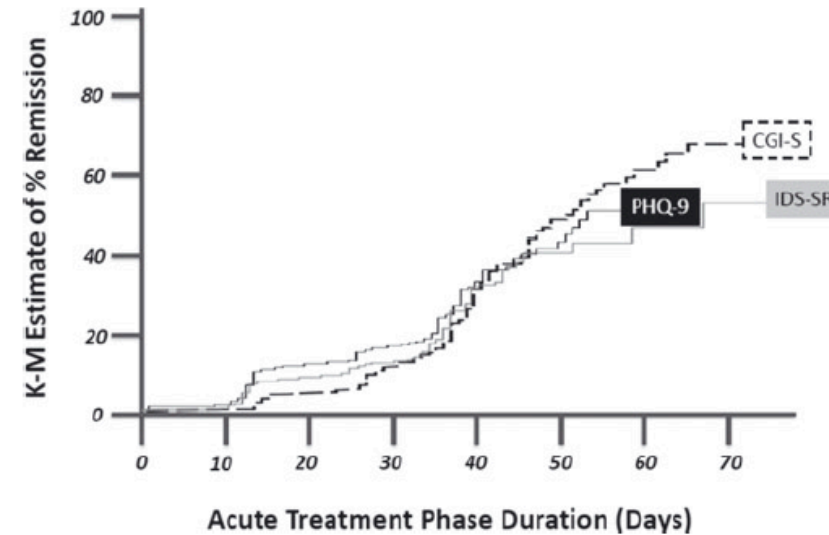
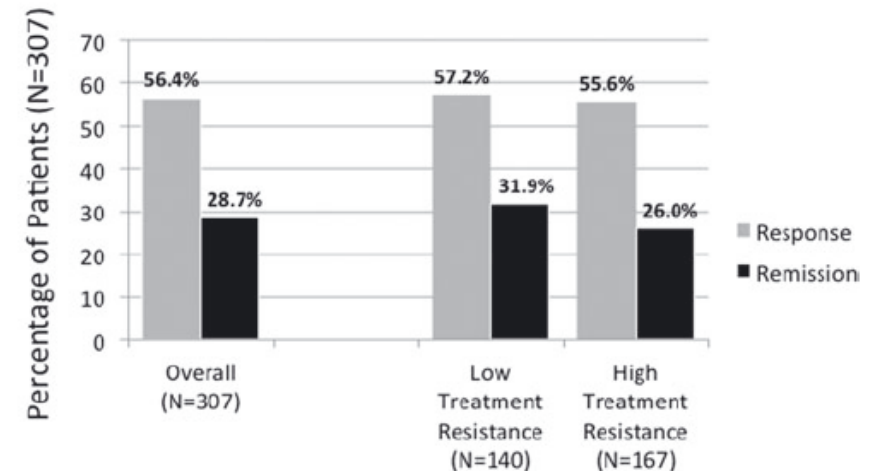


Figure 2. Kaplan–Meier survival estimate of time to first remission (CGI-S, PHQ-9, and IDS-SR outcomes).

PHQ-9 Outcomes

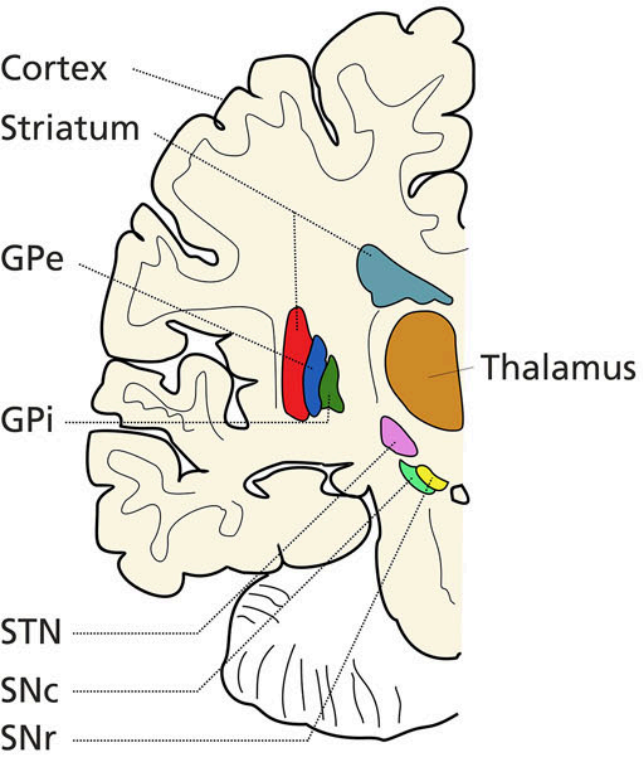


LOCF Analysis of intent-to-treat population

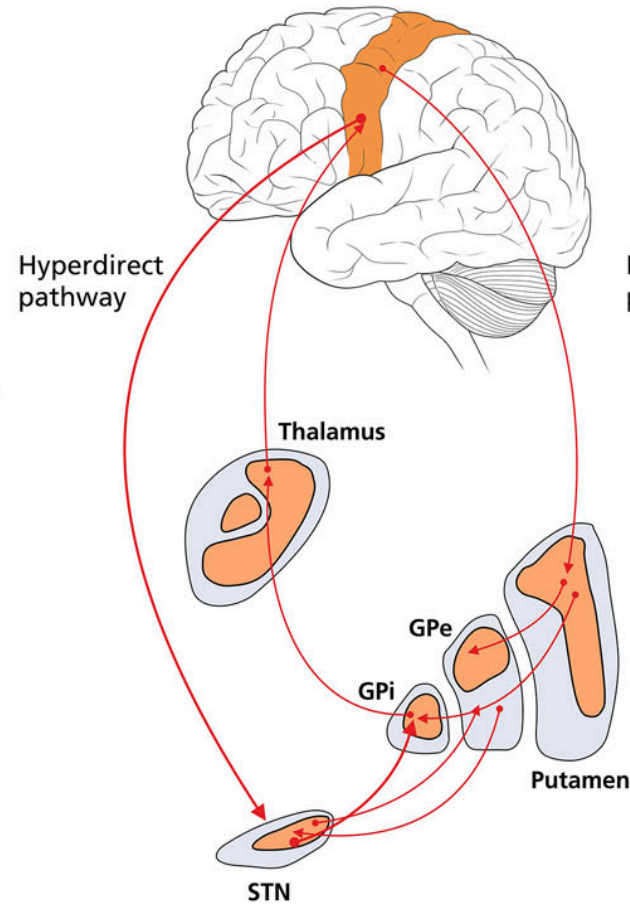
Please see text for definitions of response, remission and treatment resistance level

Cortico-basal ganglia-thalamo-cortical loop dysfunction in OCD

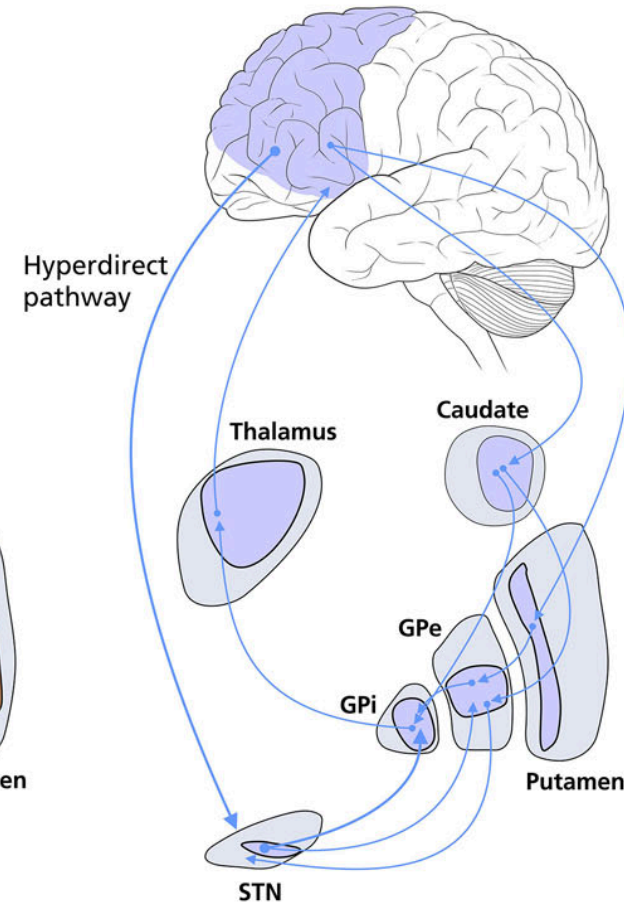
A Frontal Section



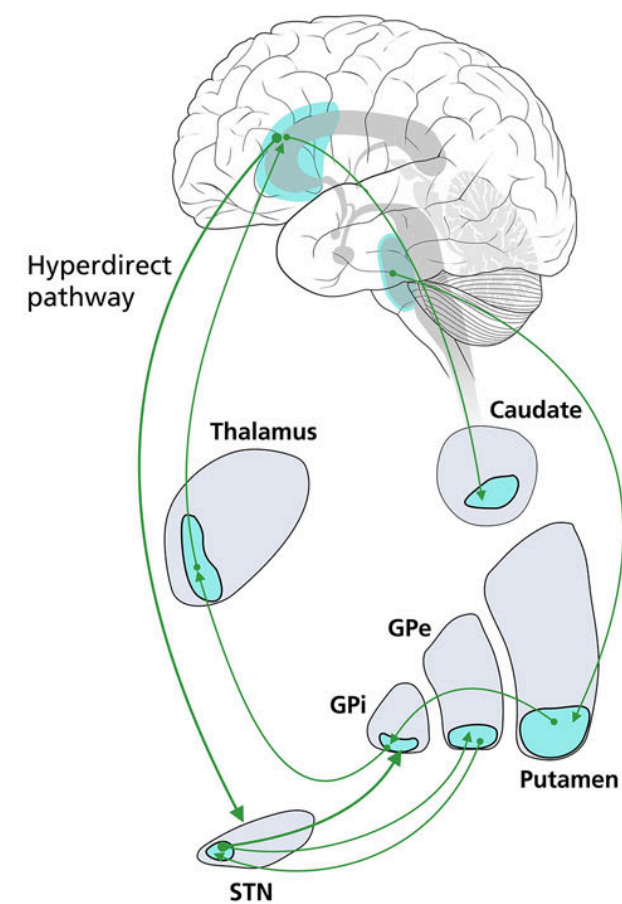
Motor Circuit



Associative Circuit



Limbic Circuit



Efficacy and Safety of Deep Transcranial Magnetic Stimulation for Obsessive-Compulsive Disorder: A Prospective Multicenter Randomized Double-Blind Placebo-Controlled Trial

Lior Carmi, Ph.D., Aron Tendler, M.D., Alexander Bystritsky, M.D., Eric Hollander, M.D., Daniel M. Blumberger, M.D., Jeff Daskalakis, M.D., Herbert Ward, M.D., Kyle Lapidus, M.D., Wayne Goodman, M.D., Leah Casuto, M.D., David Feifel, M.D., Noam Barnea-Ygael, Ph.D., Yiftach Roth, Ph.D., Abraham Zangen, Ph.D., Joseph Zohar, M.D.

TABLE 1. Demographic data and baseline clinical assessments in a randomized controlled trial of dTMS for obsessive-compulsive disorder^a

Characteristic	Active Treatment Group (N=47)		Sham Treatment Group (N=47)	
	N	%	N	%
Female	27	57.4	28	59.6
	Mean	SD	Mean	SD
Age (years)	41.1	11.97	36.5	11.38
Yale-Brown Obsessive Compulsive Scale	27.7	3.87	26.9	4.13
Clinical Global Impressions scale				
Improvement scale	5.4	1.28	5.5	1.51
Severity scale	5.1	0.71	5.0	0.89
Sheehan Disability Scale	19.3	6.43	19.5	5.83
Hamilton Depression Rating Scale (21-item) ^b	10.0	5.79	10.9	5.47

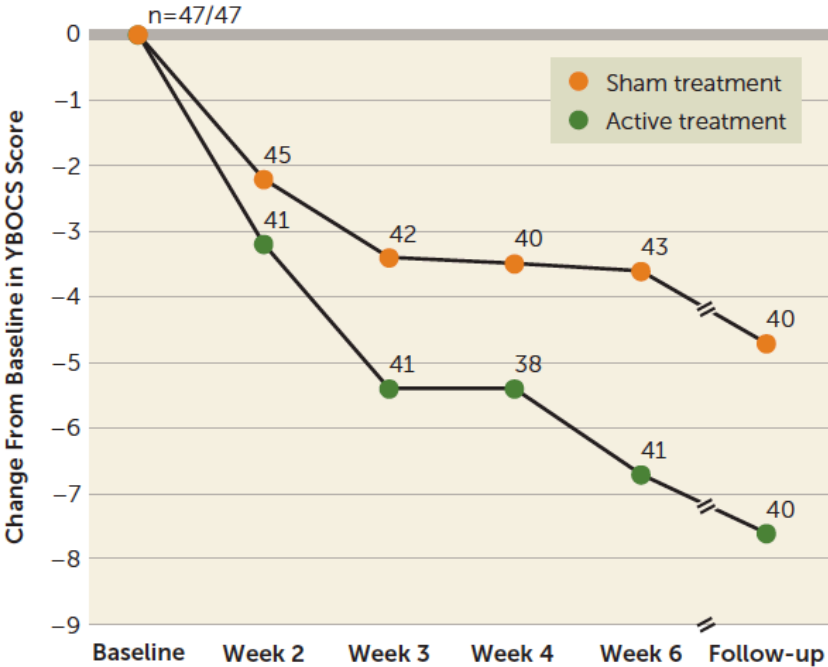
^a dTMS=deep repetitive transcranial magnetic stimulation. No significant differences between groups on any measure.
^b Two patients in each group were clinically depressed according to Hamilton Depression Rating Scale score.

- **Unique protocol:**
 - Deep TMS (dTMS) using an H-7 coil medially placed to target the dmPFC and ACC bilaterally
 - HF stimulation (20 Hz at 100% of MT, with 2-second pulse trains and 20-second ntertrain intervals, 50 trains total/2,000 pulses per session
 - Personalized, *pre-treatment symptom provocation 3-5 minutes before each treatment to “activate relevant circuits.”*

Efficacy and Safety of Deep Transcranial Magnetic Stimulation for Obsessive-Compulsive Disorder: A Prospective Multicenter Randomized Double-Blind Placebo-Controlled Trial

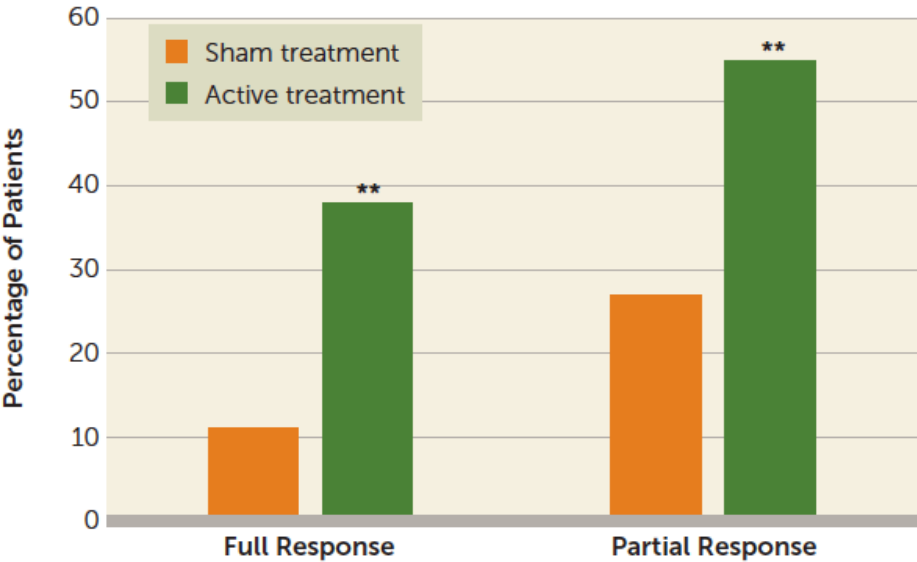
Lior Carmi, Ph.D., Aron Tendler, M.D., Alexander Bystritsky, M.D., Eric Hollander, M.D., Daniel M. Blumberger, M.D., Jeff Daskalakis, M.D., Herbert Ward, M.D., Kyle Lapidus, M.D., Wayne Goodman, M.D., Leah Casuto, M.D., David Feifel, M.D., Noam Barnea-Ygaël, Ph.D., Yiftach Roth, Ph.D., Abraham Zangen, Ph.D., Joseph Zohar, M.D.

FIGURE 2. Change from baseline in mean YBOCS score through the study for the active and sham dTMS treatment groups^a



^a dTMS=deep repetitive transcranial magnetic stimulation; YBOCS=Yale-Brown Obsessive Compulsive Scale. Each data point includes the patients with recorded YBOCS scores at that time point.

FIGURE 3. Rates of full response and individual distribution of responders and nonresponders according to YBOCS score at week 6 in the active and sham dTMS treatment groups^a



Full response was defined as a reduction of >30% in YBOCS score, and partial response as a reduction of >20%.

Who is the appropriate ECT candidate? *Diagnoses*

FDA approved for:

- Treatment resistant depression (TRD)
 - Response and remission rates at 6 weeks: ~20-60% and 15-30% respectively
 - NNT = 11 at 4 weeks, 9 at 6 weeks (Oral AD's NNT = 8, Thase ME, *J Clin Psy*, 2005)
- Many insurance companies require failure of at least 4 medication trials
 - Anthem Blue Cross and Blue Shield, the largest, in addition to requiring the failure of 4 AD's, also requires the failure of two evidence-based augmentation strategies (e.g. aripiprazole or lithium)
 - Typical course may cost \$6K – \$20K out-of-pocket
- Caution in patients with suspected BPAD, potential risk for affective switch into hypomania/mania

Predictors of rTMS response

Table 3 Univariate Analyses of Candidate Clinical Variables Evaluated as Predictors of Outcome with Acute Treatment (MADRS Total Score Change from Baseline): Open-label Trial

Variable name	Variable definition	Pooled study sample p-value (main effect for variable) (N = 158)	Direction of effect	Extended TMS group p-value (main effect for variable) (N = 73)	Direction of effect	Sham to TMS group p-value (main effect for variable) (N = 85)	Direction of effect
<i>Categorical</i>							
Age	≥55 years vs <55 years	0.296	—	0.362	—	0.364	—
Gender	Male vs female	0.124	—	0.038	Superior effect for females	0.676	—
Duration of current episode	≤2 years vs >2 years	0.955	—	0.987	—	0.799	—
Comorbid anxiety disorder	Any anxiety disorder vs none	0.007	Superior effect for no comorbid anxiety disorder	0.405	—	0.005	Superior effect for no comorbid anxiety disorder
Course of illness	First episode vs recurrent illness	0.386	—	0.021	Superior effect for single episode	0.408	—
Treatment resistance (current episode)	One adequate treatment in current episode vs more than one	0.160	—	0.885	—	0.051	Superior effect for one adequate treatment in current episode
Employment status	Employed full or part time vs unemployed	0.449	—	0.388	—	0.817	—
Atypical depression	Defined by IDS-SR criteria	0.451	—	0.267	—	0.803	—
<i>Continuous</i>							
Baseline symptom severity	MADRS total score at baseline	0.037	Superior outcome for higher baseline symptom severity (r = -0.17)	0.433	—	0.024	Superior outcome for higher baseline symptom severity (r = -0.25)
Baseline motor threshold	Motor threshold (% machine output) at baseline	0.563	—	0.054	Superior outcome for lower baseline motor threshold (r = +0.23)	0.829	—

Variables indicated in bold demonstrated a significant main effect for the predictor variable within the treatment group specified ($P < 0.10$).

—, No statistically different benefit at the specified level for the indicated treatment group.

Please see text for further discussion of results and direction of effect on outcome.

rTMS – Treatment Course

Initial Consult

- Pre-rTMS workup
- Consent

“Index” Series

- Tx 1: Motor threshold (MT) determination
- Tx 2 + N: Consecutive, daily treatments with target stimulus of 100-120% MT (Mon- Fri)
- Serial symptom and side-effect monitoring
- 28 consecutive treatments

Tapering Treatment

- 6- 10 sessions tapered from daily to twice weekly until completion
- ***There is no current evidence support maintenance rTMS, however “booster treatments” may be indicated for responders.***
- Initial response positive predictor for future response. Insurance often covers another course for relapse.

rTMS – Durability of response

Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study

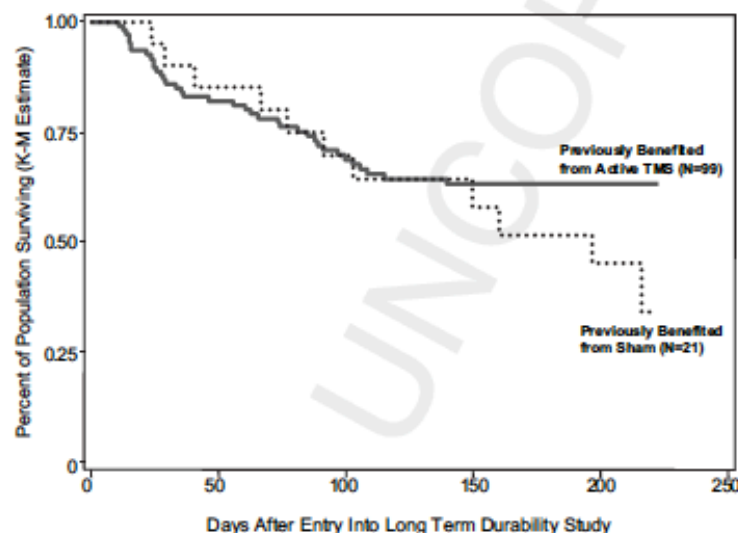
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Durability of TMS antidepressant effect		3
Table 1 Summary of prior studies assessing the durability of the acute antidepressant effect of TMS		
Study	Design	Outcome
Dannon et al. ⁸	6-mo follow-up in acute responders to TMS or ECT	• 20% relapse rate in both groups
O'Reardon et al. ⁹	Maintenance TMS for major depression over 6 mo to 6 y	• 7/10 received moderate or marked benefit • 3/10 maintained on TMS monotherapy
Fitzgerald et al. ¹⁰	TMS re-introduction in 19 medication-free, TRD patients who initially responded to TMS	• Relapses occurred over 6-12 mo • TMS produced comparable benefit with reintroduction
Demirtas-Tatlidede ¹¹	16 acute TMS responders followed over 4 y	• 50% benefited from TMS reintroduction • Mean interval between TMS retreatment was 4.9 mo
Cohen et al. ¹²	204 initial TMS remitters followed naturalistically	• Median times in remission was 120 d • Younger age and greater number of acute TMS sessions predicted longer-term benefit

rTMS – Durability of response

Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study

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Colleen Loo,^j Mustafa H. H
Sheila M. Dowd,^a Mark A. I



NOTE: Both groups are shown for contrast, however, because these groups are no longer fully randomized samples at entry into the durability of effect follow up study, inferential comparisons are not statistically appropriate (please see text for details).

Figure 3 Kaplan-Meier survival curve estimate of time to first reintroduction of TMS during the 24-week, long-term durability of effect study for patients previously benefiting from acute treatment with active TMS (n = 99) and for patients previously benefiting from sham treatment (n = 21).

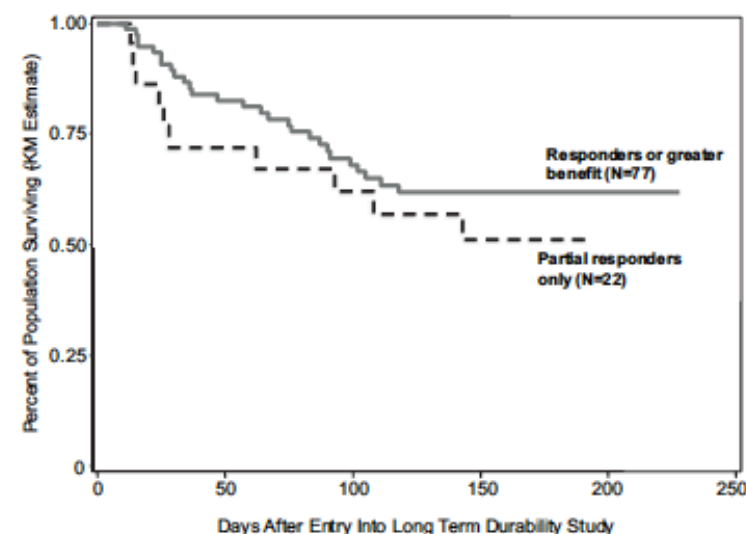


Figure 4 Kaplan-Meier survival curve estimate of time to first reintroduction of TMS during the 24-week, long-term durability of effect study for patients previously benefiting from acute treatment with active TMS: comparison of full response or greater benefit cohort (n = 77) with the partial response only cohort (n = 22).

rTMS – Risks and Side Effects

Side effect	Single-pulse TMS	Paired-pulse TMS	Low frequency rTMS	High frequency rTMS	Theta burst
Seizure induction	Rare	Not reported	Rare (usually protective effect)	Possible (1.4% crude risk estimate in epileptic patients; less than 1% in normals)	Possible (one seizure in a normal subject during cTBS) (see para 3.3.3)
Transient acute hypomania induction	No	No	Rare	Possible following left prefrontal stimulation	Not reported
Syncope	Possible as epiphenomenon (i.e., not related to direct brain effect)				Possible
Transient headache, local pain, neck pain, toothache, paresthesia	Possible	Likely possible, but not reported/ addressed	Frequent (see para. 3.3)	Frequent (see para. 3.3)	Possible
Transient hearing changes	Possible	Likely possible, but not reported	Possible	Possible	Not reported
Transient cognitive/ neuropsychological changes	Not reported	No reported	Overall negligible (see Section 4.6)	Overall negligible (see Section 4.6)	Transient impairment of working memory
Burns from scalp electrodes	No	No	Not reported	Occasionally reported	Not reported, but likely possible
Induced currents in electrical circuits	Theoretically possible, but described malfunction only if TMS is delivered in close proximity with the electric device (pace-makers, brain stimulators, pumps, intracardiac lines, cochlear implants)				
Structural brain changes	Not reported	Nor reported	Inconsistent	Inconsistent	Not reported
Histotoxicity	No	No	Inconsistent	Inconsistent	Not reported
Other biological transient effects	Not reported	Not reported	Not reported	Transient hormone (TSH), and blood lactate levels changes	Not reported

rTMS – Contraindications

- Conductive, ferromagnetic, or other magnetic-sensitive metals implanted in their head within 30 cm of the treatment coil (e.g. cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents, bullet fragments, jewelry and hair barrettes). Metallic dental implants and fillings are *not* contraindications
- History (or family history) of seizure or epilepsy (relative)
- History of stroke, head injury, severe headaches, or unexplained seizures
- Presence of other neurological disease that may be associated with an altered seizure threshold (such as CVA, cerebral aneurysm, dementia, increased intracranial pressure, head trauma, or movement disorder)
- Concurrent medication use such as tricyclic antidepressants, neuroleptic medications, or other drugs that are known to lower the seizure threshold (relative)

- BPAD/MDD with psychotic features
- Active substance use disorder

rTMS – Treatment Day 1

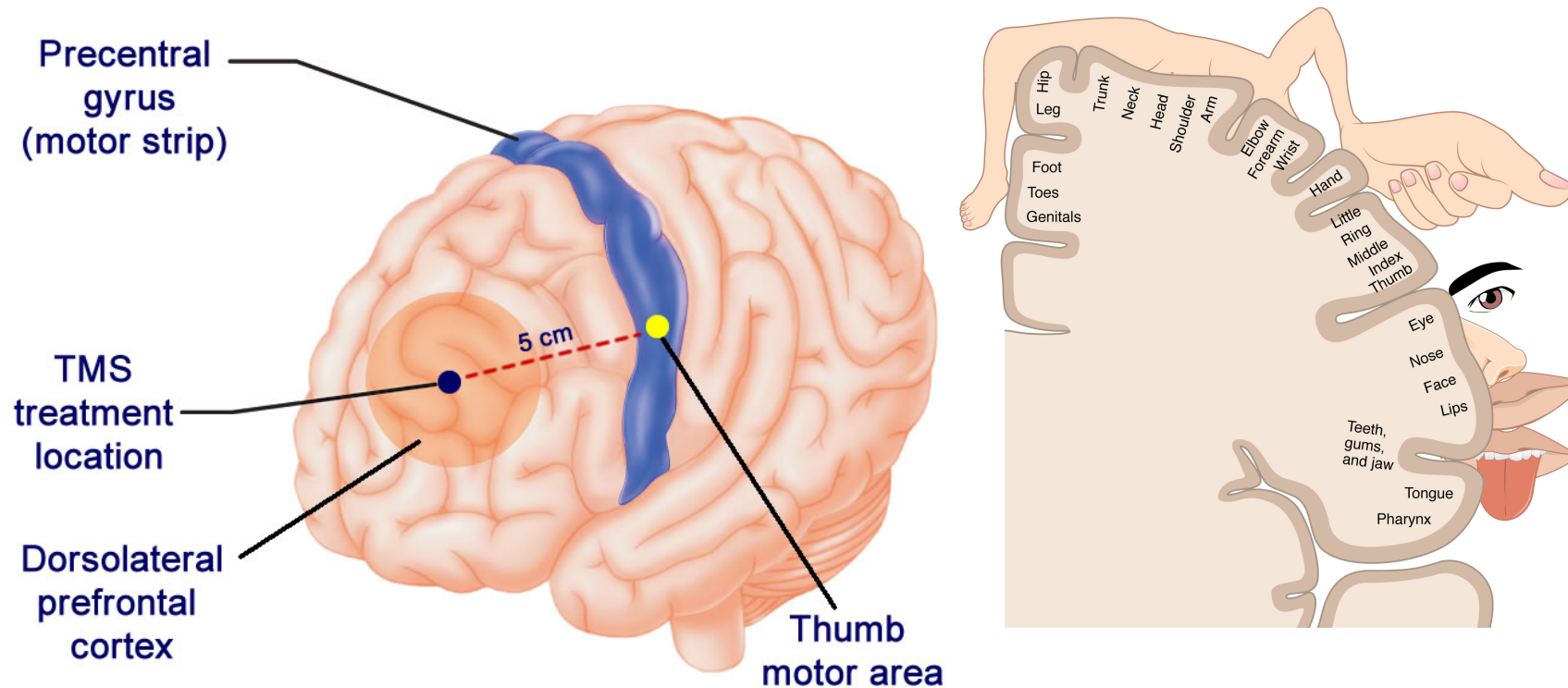


Motor threshold (MT) determination:

- Minimum single pulse TMS energy need to observe an abductor pollicis brevis contraction
- Typically stable over time, though may be re-assessed q1-2 weeks depending on response
- Observed visually vs. motor evoked potential (MEP) recording

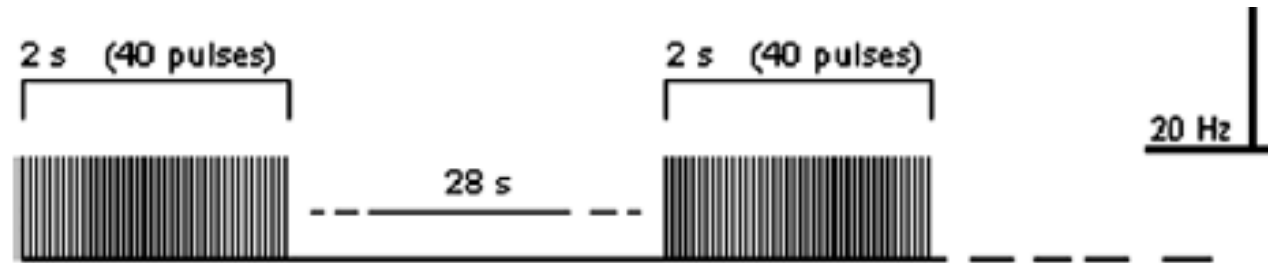
rTMS – Treatment Day 1

Motor threshold (MT) determination:



- Takes about 30-60 minutes
- First treatment on day of MT (total of 1.5 hour appt)
- Slow escalation to 120% of MT

rTMS – Day 2 – 34



- 40 min treatments, five days per week
- Performed by rTMS technician
- Earplugs/earbuds and cap
- Check medications at every treatment!
- Can eat, drink, drive before and after
- No anesthesia

rTMS – Common clinic setting characteristics

1. Multiple business paradigms: traditional private practices incorporating TMS, TMS device partnerships, networked practices, academic institutions, dedicated TMS centers.
2. Training often provided by the manufacturer for both physicians and ancillary staff: a qualified *physician* must perform motor threshold procedure but routine treatments may be performed by a trained technician.
3. No formal credentials or licensure are required for the technician other than certification on the device that is being used to administer the treatment. *It is recommended that technicians be trained in BLS and a physician always be available for treatment emergent issues (e.g. seizure).*
4. No uniform requirements regarding the physical care environment.

Practical considerations in formulating candidacy

- Financial considerations (often *not* covered by Medicaid, potentially by Medicare)
- Provider/geographic access
- Physical limitations, e.g. is the patient capable of sitting still for at least 1 hour
- Given the high standard for insurance coverage, e.g. TRD with well documented treatment failures, is the patient *too* severely ill or at risk for rTMS?
- What is the patient's preference? Might the patient be more appropriate for ECT/ketamine/esketamine?

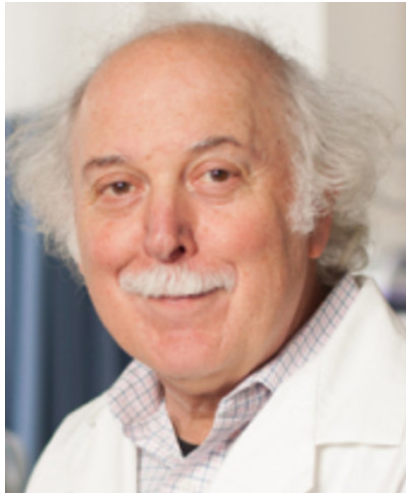
Role of the outpatient psychiatrist

- Finding a place to refer, know your local resources.
- Pre-referral workup: Physical examination, CMP, CBC, TSH, EKG, urine toxicology, imaging (*not required, but if indicated*)
- Communicating with the rTMS consultants.
 1. You are the BEST source for providing context for the referral; collateral is invaluable throughout an rTMS course
 2. Help the consultant understand the overall formulation, e.g. What is a reasonable treatment goal for this patient based on pre-morbid functioning?
 3. Provide further augmentation support via psychotropic optimization *or* psychotherapy; rTMS pairs well with evidence-based psychotherapy (e.g. CBT)
 4. Providing a comprehensive past-psychiatric history, especially with past medication trials and description of response
 5. Provide ongoing support in evaluating whether the patient needs an alternative therapy
 6. Work with the patient on a relapse prevention plan.

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Opportunities for CME and CEU's in ECT:
Yale-IPS Mini-Fellowship (2.5 day experience)
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