1

DISCLOSURES

Source	Research Funding	Honorarium/Advisor/ Consultant/Other	Employee	Speaker's Bureau	In-kind Services	Stock or Equity	Travel
American Academy of Child and Adolescent Psychiatry (AACAP)		X (Donated to AACAP)					
Brain and Behavior Research Foundation (NARSAD)	X						
Clinical TMS Society		X					X
Engrail Therapeutics, Inc.		X					
MagVenture, Inc					X		
Mayo Clinic	X		X				
Neuronetics, Inc	X				X		
NeoSync, Inc	X						
NIMH	X						
Pfizer	X						
Procter & Gamble Company		X					
Myriad Neuroscience		X (Donated to NNDC)			X		
TMS Health Education							X
Salience TMS Neuro Solutions		X (Unpaid)					
Sunovion		X					

2

LEARNING OBJECTIVES

- To review recent research focused on the application of TMS to adolescents and young adults.
- To discuss challenges and future related innovations direction to address this unmet need

3

THE CHALLENGE…

Hetrick SE, McKenzie JE, Bailey AP, Sharma V, Moller CI, Badcock PB, Cox GR, Merry SN, Meader N. New generation antidepressants for depression in children and adolescents: a network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 5. Art. No.: CD013674. DOI: 10.1002/14651858.CD013674.pub2. Accessed 30 May 2021.

4

DEFICITS AND OPPORTUNITIES

frontiers in Psychiatry

REVIEW
published: 13 April 2021
doi: 10.3389/fpsyt.2021.642847

Repetitive Transcranial Magnetic Stimulation for Adolescent Major Depressive Disorder: A Focus on Neurodevelopment

Lindsay M. Oberman, Megan Hynd, Dylan M. Nielson, Kenneth E. Towbin, Sarah H. Lisanby and Argyris Stringaris*

National Institute of Mental Health, Bethesda, MD, United States

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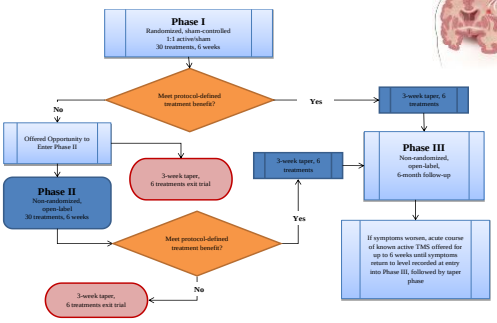


Croarkin PE, Elmaadawi AZ, Aaronson ST, Schrodt GR, Holbert RC, Verdoliva S, Heart KL, Demitrack MA, Strawn JR. Left Prefrontal Transcranial Magnetic Stimulation for Treatment-Resistant Depression in Adolescents: A Double-Blind, Randomized, Sham-Controlled Trial. Neuropsychopharmacology 2021 Jan;46(2):462-469. doi: 10.1038/s41386-020-00829-y. Epub 2020 Sep 12.

6

Summary of Key Demographics and Clinical Variables at Baseline

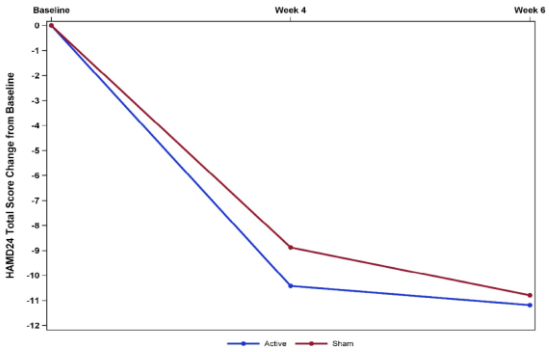
Variable	Treatment Group		p-value
	Sham (N = 55)	Active (N = 48)	
Gender N (%)			0.6123
Baseline Symptom Severity			
HAMD24 Total Score			0.3377
N	55 (Sham)	48 (Active)	
Mean (SD)	29.5 (8.69)	28.8 (5.75)	
Median	28.0	28.5	
Min, Max	18.0, 54.0	19.0, 43.0	
Duration of Current Episode			0.0721
N	55	48	
Mean (SD)	25.5 (4.41)	26.9 (4.43)	
Median	22.0	21.0	
Min, Max	12.0, 37.0	11.0, 31.0	
Age at Current Episode Onset			0.7384
N	55	48	
Mean (SD)	32.3 (7.16)	33.1 (8.41)	
Median	33.0	32.0	
Min, Max	19.0, 56.0	17.0, 42.0	
Current Episode Length			0.3510
N	55	48	
Mean (SD)	62.6 (16.03)	61.3 (10.60)	
Median	61.0	64.0	
Min, Max	21.0, 89.0	40.0, 84.0	
Number of Prior Episodes			0.7154
N	55	48	
Mean (SD)	5.1 (6.68)	5.1 (6.72)	
Median	3.0	3.0	
Min, Max	4.0, 7.0	4.0, 7.0	
Number of Prior Episodes of Major Depressive Disorder			0.7145
N	55	48	
Mean (SD)	26.8 (7.54)	26.4 (8.80)	
Median	21.0	20.0	
Min, Max	11.0, 36.0	6.0, 35.0	
Age			0.5291
Mean (SD)	33.0 (8.17)	32.4 (8.80)	
Median	32.0	31.0	
Min, Max	18.0, 56.0	17.0, 42.0	
Gender N (%)			0.6211
Female	32 (58.2%)	28 (58.3%)	
Male	23 (41.8%)	20 (41.7%)	
Current Major Depressive Disorder			
Major Depressive Disorder	55 (100.0%)	48 (100.0%)	
Non-Major Depressive Disorder	0 (0.0%)	0 (0.0%)	
Major Depressive Disorder History N (%)			0.2405
Single episode	13 (23.6%)	9 (18.8%)	
Recurrent episodes	42 (76.4%)	39 (81.3%)	
Number of Current Episodes			0.8888
N	55	48	
Mean (SD)	13.8 (8.36)	13.9 (9.01)	
Median	12.0	13.2	
Min, Max	1.5, 33.9	1.8, 36.2	
<24 months N (%)	50 (90.9%)	43 (89.6%)	0.8504
≥24 months N (%)	5 (9.1%)	5 (10.4%)	
Number of Prior Episodes			0.7154
0	4 (7.3%)	2 (4.2%)	
1	30 (54.5%)	22 (45.8%)	
2	15 (27.3%)	17 (35.4%)	
3	4 (7.3%)	5 (10.4%)	
4	2 (3.6%)	1 (2.1%)	
5	0 (0.0%)	1 (2.1%)	
Bipolar Disorder Diagnosis			0.7145
None	19 (34.5%)	22 (45.8%)	
Any	36 (65.5%)	26 (54.2%)	
Prior Treatment History N (%)			
Prior ECT Treatment	0 (0.0%)	0 (0.0%)	0.0000
Prior Inpatient Hospitalization for Depression	9 (16.4%)	9 (18.8%)	0.7155
Prior Psychotherapy	10 (18.2%)	7 (14.6%)	0.6228
Manic/Hypomania by YMRS (Total Score > 20)	0 (0.0%)	0 (0.0%)	N/A
Baseline Medication Dosage			
Mean	0.95	0.94	
Median	0.95	0.94	
Min, Max	0.35, 1.27	0.42, 1.30	

p-value from Chi-square or Fisher's exact test for categorical variables and t-test for continuous variables.

Subjects within ATR Medication Resistance Level 0 and 5 do not meet the study inclusion/exclusion criteria. There were documented no protocol deviations.

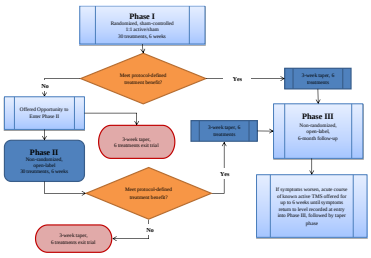
Strawn et al. Treatment-Resistant Depression in Adolescents: Clinical Features and Measurement of Treatment Resistance. Journal of Child and Adolescent Psychopharmacology 2020; 30(4):262-266.

7



8

REINTRODUCTION TMS AS A STRATEGY FOR MAINTENANCE TREATMENT FOR ADOLESCENTS WITH TREATMENT RESISTANT DEPRESSION



9

PHASE III

Entering Phase III n=65

Completed Phase III n=41

Discontinued prior to end of month 6 n=24

Patients entering retreatment n= 28

- Phase I Active to Phase II Active
- Phase I Sham to Phase II Active
- Phase I Active to Phase III
- Phase I Sham to Phase III

10

PHASE III

Reasons for Discontinuation (n=24)

- Satisfactory Response (efficacy) n=1
- Unsatisfactory Response (efficacy) n=5
- Adverse Event n=2
- Failed to Return n=7
- Subject Request n=4
- Symptoms Worsened n=1
- Other n=4

11

PHASE III OUTCOMES HAMD24

	Baseline n Score (SD)	*Month 3 n Score (SD) Change*	*Month 3 n Score (SD) Change*
Phase I Active	17 27.3 (5.86)	16 7.7 (7.43) -19.1 (7.99)	14 5.9 (6.13) -22.1 (6.58)
Phase I Active to Phase II Active	8 27.3 (3.54)	8 12.1 (8.13) -15.1 (10.20)	5 7.4 (6.66) -19.8 (6.94)
Phase I Sham to Phase II Active	13 26.2 (3.31)	13 8.1 (7.48) -18.1 (7.32)	11 4.3 (3.82) -21.3 (2.41)
Phase I Sham	17 28.2 (6.62)	16 8.7 (7.13) -19.9 (7.96)	11 4.4 (4.92 -24.9 (4.91)

12

PHASE III PATIENTS WITH RETREATMENT HAMD24

	Baseline Score (SD)	Pretreatment Change from Baseline	After treatment Change from Baseline	Number Receiving Retreatment	Mean number of Retreatments (Range)
Phase I Active	13.0 (6.49)	2.2 (8.03)	2.1 (5.79)	12	23 (9-30)
Phase I Active to Phase II Active	11.5 (4.95)	-4.0 (1.41)	9.5 (4.95)	2	30 (30)
Phase I Sham to Phase II Active	6.5 (5.86)	11.7 (7.47)	6.8 (11.11)	6	17 (5-30)
Phase I Sham	10.8 (6.3)	7.9 (5.72)	0.5 (9.70)	8	21 (1-30)

13

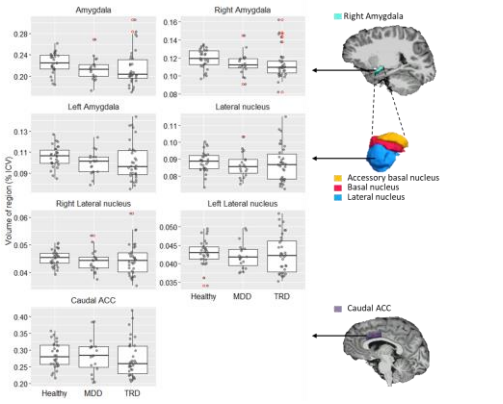
Jeffrey R. Strawn, MD

NEUROSTRUCTURAL IMPACT OF TRD IN ADOLESCENTS AND POTENTIAL TREATMENT EFFECTS OF TMS

Bhedita Seewoo

Characteristic	Healthy	MDD	TRD	Active rTMS	Sham rTMS
n	30	19	34	18	7
Female	70%	57.9%	58.8%	66.7%	71.4%
Age (SD)	15.60 (2.25)	15.2 (1.8)	16.4 (1.8)	16.3 (2.0)	17.5 (1.2)
CDRS-R (SD)	19.1 (2.8)	54.1 (8.2)	59.6 (11.4)	50.2 (15.1)	61.4 (8.4)

14



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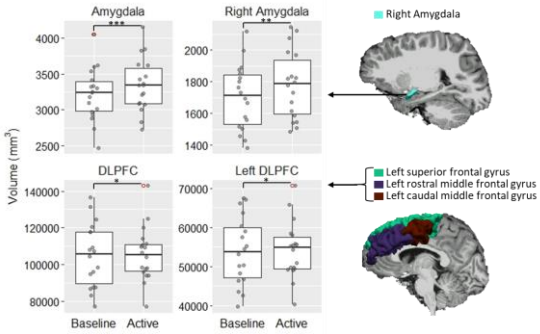


16

Clinical Effectiveness of 1 Hz/20 Hz Bilateral rTMS Treatment in Adolescents with Major Depressive Disorder

Salience TMS Neuro Solutions

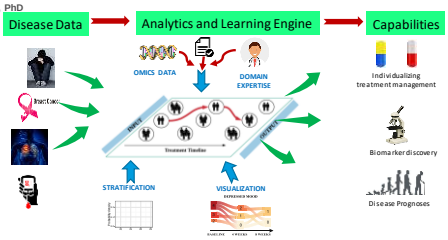
UNIVERSITY OF TORONTO

- Multisite, naturalistic treatment
- N=201
- Ages 12-22
- 1 Hz delivered to the right dorsolateral prefrontal cortex for 360 pulses, followed by 20 Hz delivered to the left dorsolateral prefrontal cortex for 1200 pulses
- 30-36 sessions

17

Arjun Athreya, PhD

Analytics and Machine Learning Framework for Omics and Clinical Big Data (ALMOND)

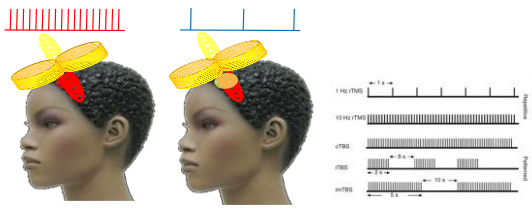


Athreya et al. (US Patent Pending 16/221,073)

Athreya AP, et al. Prediction of short-term antidepressant response using probabilistic graphical models with replication across multiple drugs and treatment settings. Neuropsychopharmacology. Jun;46(7):1272-1282. doi: 10.1038/s41386-020-00943-x. Epub 2021 Jan 15.

18

PRECISION MEDICINE APPROACHES FOR BRAIN STIMULATION

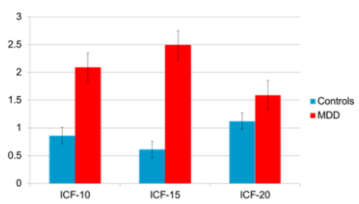


10 Hz – 20 Hz Excitatory

1 Hz Inhibitory

19

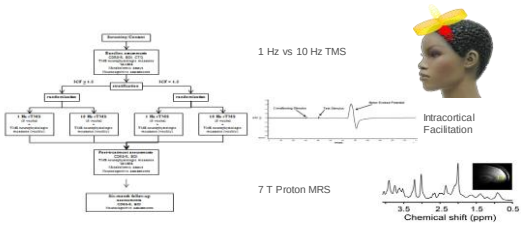
Intracortical Facilitation



Croarkin PE, et al. Evidence for increased glutamatergic cortical facilitation in children and adolescents with major depressive disorder. JAMA Psychiatry. 2013 Mar;70(3):291-9. doi: 10.1001/2013.jamapsychiatry.24.

20

GLUTAMATERGIC AND GABAERGIC BIOMARKERS FOR TMS TREATMENT OF DEPRESSION IN ADOLESCENTS



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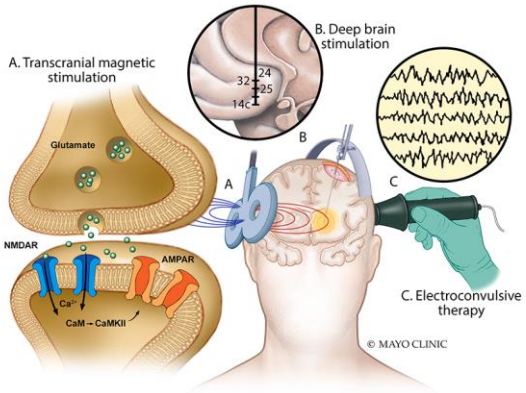

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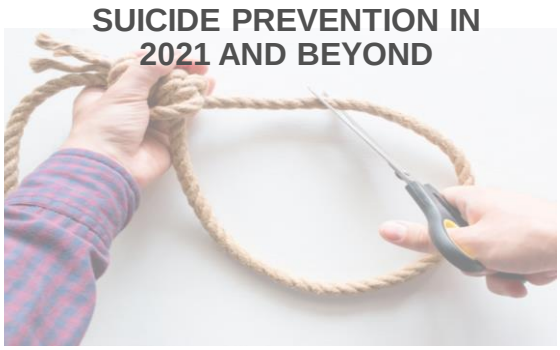

23

Utku Kucuker, MD

SYSTEMATIC REVIEW article

Front. Hum. Neurosci. | doi: 10.3389/fnhum.2021.660926

A Systematic Review of Neuromodulation Treatment on Suicidality Provisionally accepted The final, formatted version of the article will be published soon. Notify me

Utku Kucuker[1], Ammar Almorsy[1], Ayse I. Sonmez[1], Anna N. Ligezka[1], Deniz Doruk Camsari[1], Charles Lewis[1] and Paul Croarkin[1]*

[1]Mayo Clinic, United States
[2]Department of Psychiatry, Medical School, University of Minnesota, United States

Introduction: Neuromodulation is an important group of therapeutic modalities for neuropsychiatric disorders. Prior studies have focused on efficacy and adverse events associated with neuromodulation. Less is known regarding the influence of neuromodulation treatments on suicidality. This systematic review sought to examine the effects of various neuromodulation techniques on suicidality.
Methods: A systematic review of the literature from 1940 to 2020 following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline was conducted. Any reported suicide-related outcome in reports were considered as a putative measure of treatment effect on suicidality.
Results: The review identified 129 relevant studies. There was evidence that transcranial direct current stimulation was superior to sham in decreasing suicidal ideation in a randomized, controlled trial. Electroconvulsive therapy, magnetic seizure therapy, and repetitive transcranial magnetic stimulation treatments may decrease suicidality. There was limited literature focused on the potential protective effect of vagal nerve stimulation with respect to suicidal ideation. Data were mixed regarding the potential effects of deep brain stimulation on suicidality.
Conclusions: Future prospective studies of neuromodulation that focus on the primary outcome of suicidality are urgently needed.

Keywords: Suicide, Electroconvulsive Therapy, Repetitive transcranial magnetic stimulation, transcranial direct current stimulation, Vagal nerve stimulation (VNS), Deep brain stimulation

Received: 26 Jan 2021; Accepted: 27 May 2021;

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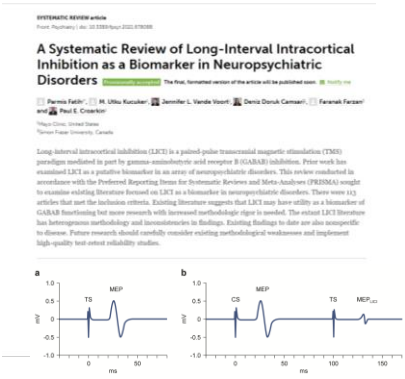
24



SYSTEMATIC REVIEW article

Front. Psychiatry | doi: 10.3389/fpsyt.2022.878088

A Systematic Review of Long-Interval Intracortical Inhibition as a Biomarker in Neuropsychiatric Disorders

Provisionally accepted The first, formatted version of the article will be published soon. Notify me

Parmis Fatih[1], M. Utku Kucuker[1], Jennifer L. Vande Voort[1], Deniz Doruk Camsari[1], Faranak Farzan[2] and Paul E. Croarkin[1]

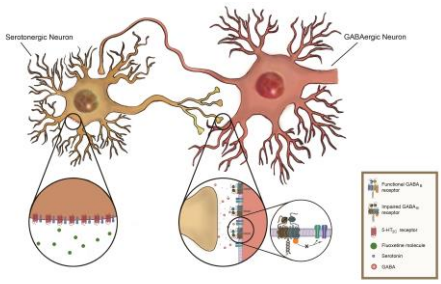
[1]Mayo Clinic, United States
[2]Simon Fraser University, Canada

Long-interval intracortical inhibition (LICI) is a paired-pulse transcranial magnetic stimulation (TMS) paradigm mediated in part by gamma-aminobutyric acid receptor B (GABAB) inhibition. Prior work has examined LICI as a putative biomarker in an array of neuropsychiatric disorders. This review conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) sought to examine existing literature focused on LICI as a biomarker in neuropsychiatric disorders. There were 113 articles that met the inclusion criteria. Existing literature suggests that LICI may have utility as a biomarker of GABAB functioning but more research with increased methodologic rigor is needed. The extant LICI literature has heterogeneous methodology and inconsistencies in findings. Existing findings to date are also nonspecific to disease. Future research should carefully consider existing methodological weaknesses and implement high-quality test-retest reliability studies.

Parmis Fatih, MD

25

LICI DEFICITS AS A MARKER OF TREATMENT RESISTANCE IN ADOLESCENTS MAJOR DEPRESSIVE DISORDER

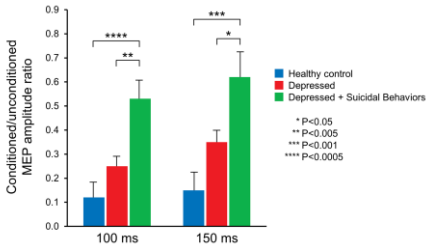


Croarkin PE, Nakonezny PA, Husain MM, Port JD, Melton T, Kennard BD, Emslie GJ, Kozel FA, Daskalakis ZJ. Evidence for pretreatment LICI deficits among depressed children and adolescents with nonresponse to fluoxetine. Brain Stimul 2014;7:243-251.

26

Charles P. Lewis, M.D.

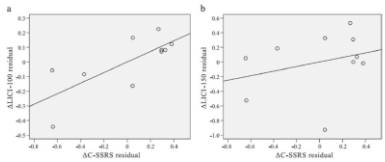
Biomarkers of Suicidality in Adolescents with Major Depressive Disorder



Lewis CP, Nakonezny PN, Blacker CJ, Vande Voort JL, Port JD, Worrell GA, Jo HJ, Daskalakis ZJ, Croarkin PE. Cortical Inhibitory Markers of Suicidality in Depressed Adolescents. Neuropsychopharmacology. 2018 Aug; 43(9):1822-1831.

27

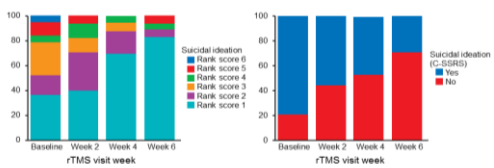
GABA$_B$ AND SUICIDAL IDEATION IN DEPRESSED ADOLESCENTS



Lewis CP, et al. Preliminary evidence of an association between increased cortical inhibition and reduced suicidal ideation in adolescents treated for major depression. J Affect Disord. 2019;244:21-24.

28

10 HZ RTMS AND ADOLESCENT SUICIDALITY



Croarkin et al. High-frequency repetitive TMS for suicidal ideation in adolescents with depression. J Affect Disord. 2018 Oct 15;239:282-290

29

Neuromodulation: Technology at the Neural Interface
Received: January 25, 2021 Revised: April 4, 2021 Accepted: April 19, 2021
(onlinelibrary.wiley.com) DOI: 10.1111/ner.13455

A Systematic Review of the Safety and Tolerability of Theta Burst Stimulation in Children and Adolescents

Rana Elmaghraby, MD; Qi Sun, MD; Can Ozger, BS; Julia Shekunov, MD; Magdalena Romanowicz, MD; Paul E. Croarkin, DO, MS

ABSTRACT

Objectives: Theta burst stimulation (TBS) is often used in clinical practice and research protocols for adults with neuropsychiatric disorders. There are substantial knowledge gaps related to the application of TBS in children and adolescents. This systematic review examined the safety and tolerability of TBS in children and adolescents.

Materials and Methods: A systematic review of human TBS studies in children and adolescents was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The following inclusion criteria were applied: 1) articles in English language only; 2) studies that included child and adolescent participants (up to 21 years of age); 3) studies that administered intermittent TBS or continuous TBS or both to participants; 4) studies that had an outcome measure; and 5) availability of full text material. The primary outcome measures were tolerability and safety. When feasible, the clinical effects were reviewed.

Results: Twenty relevant articles met the criteria for inclusion. The reported adverse events were mild and similar to what is noted in adult studies. The most common symptom was headache. One case report described a seizure induced by TBS. Collectively, the studies were heterogeneous but the methodologic quality of randomized trials was high.

Conclusions: TBS interventions in children may have similar safety, tolerability, and feasibility as compared to adults. However, long-term, follow-up studies of TBS are lacking. Future dose-ranging studies with systematic assessment of adverse events will be important in the translation of findings with TBS from adults to youth.

Keywords: Adolescents, children, systematic review, theta burst stimulation, transcranial magnetic stimulation

Conflict of Interest: Paul E. Croarkin has received research grant support from Neuronetics, Inc. and NeoSync, Inc. He has received grant in-kind (equipment support for research studies) from Neuronetics, Inc. and MagVenture, Inc. He has served as a consultant for Myriad Neuroscience and Procter & Gamble. The other authors have no other financial disclosures or conflicts of interest.

30

THETA BURST STIMULATION (TBS) IN YOUTH WITH MAJOR DEPRESSIVE DISORDER

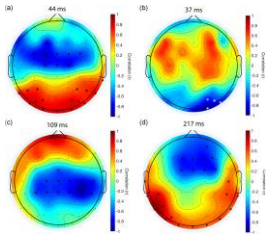
Faranak Farzan, Ph.D.

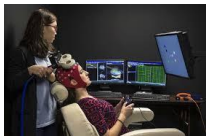
- N=20
- Ages 16-24
- 10 treatment sessions over 2 weeks
- Sequential Bilateral TBS (1800 pulses of continuous TBS to the Right DLPFC and 1800 pulses of intermittent to the Left DLPFC at 80% active motor threshold)
- 18 completers with a significant reduction in Hamilton Rating Scale for Depression 17 scores ($p < 0.001$)
- Tolerable treatment

Dhami P, et al. Feasibility and clinical effects of theta burst stimulation in youth with major depressive disorders: An open-label trial. Journal of Affective Disorders. 2019;258:66-73.

31

TMS-EEG Biomarkers





Dhami P et al. Neurophysiological markers of response to theta burst stimulation in youth depression. Depression and Anxiety. 2021 Feb;38(2):172-184. doi: 10.1002/da.23100. Epub 2020 Oct 1.Depress Anxiety. 2021. PMID: 33001549

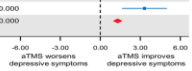
32

ACCELERATED TMS

Ayse Irem Sonmez, M.D

Study name	Statistics for each study						
	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-value	P-value
Baeken et al, 2013*	0.735	0.295	0.087	0.157	1.313	2.494	0.013
Duprat et al, 2016*	0.737	0.198	0.039	0.349	1.126	3.719	0.000
Fitzgerald et al, 2018*	0.826	0.128	0.016	0.576	1.076	6.466	0.000
Loo et al, 2007*	1.369	0.272	0.074	0.836	1.903	5.034	0.000
McGir et al, 2015	1.656	0.317	0.100	1.035	2.277	5.230	0.000
Dardenne et al, 2018	1.715	0.407	0.166	0.916	2.513	4.208	0.000
Holtzheimer et al, 2010	1.742	0.378	0.143	1.001	2.483	4.607	0.000
Williams et al, 2018	3.322	0.864	0.747	1.627	5.016	3.843	0.000
Overall (I-squared = 71%, P=0.001)	1.269	0.188	0.035	0.902	1.637	6.767	0.000

*Active arms only



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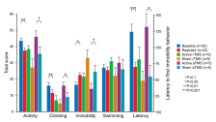
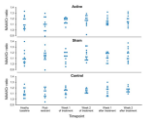
33

Jennifer Rodger, PhD

A Preclinicial Model of Accelerated TMS

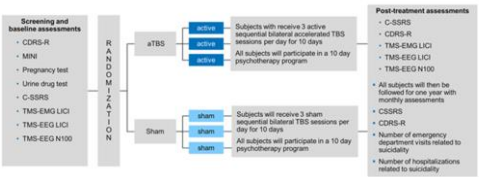
Bhedita Seewoo





Seewoo B, Feindel K, Etherington S, Hennessy L, Croarkin PE, Rodger J. Validation of the Chronic Restraint Stress Model of Depression in Rats and Investigation of Standard vs. Accelerated rTMS Treatment. The 58th Annual Meeting of the American College of Neuropsychopharmacology. Vol 44. Orlando, FL; 2019:122-123.

34



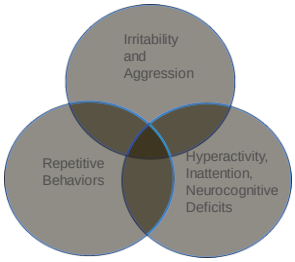
35

Session	Participants	Topic
1	Adolescent and Parent	Chain analysis and safety plan
2	Adolescent and Parent	Review adherence, psychoeducation, and safety plan
3	Adolescent	Reasons for living module
4	Adolescent	Mindfulness module
5	Adolescent	Distress tolerance module
6	Adolescent and Parent	Review sessions 3-5 with parent
7	Adolescent	Problem-solving module
8	Adolescent	Socialization and support module
9	Adolescent	Wellness and relapse prevention module
10	Adolescent and Parent	Review work with parent

36

AUTISM SPECTRUM DISORDER: ASSOCIATED SYMPTOMS

- Hyperactivity
- Short Attention Span
- Impulsivity
- Irritability
- Aggressiveness
- Severe Tantrums
- Hypersensitivity to sensory stimuli
- Abnormal eating
- Affective/Mood Lability
- Abnormal emotional reactions
- Anxiety
- Self-Injurious Behaviors



37

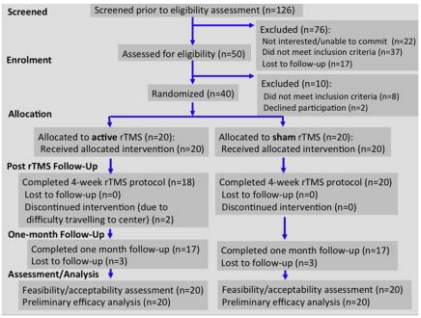
PREDICTORS OF OUTCOME IN ASD

LANGUAGE OUTCOME | IQ | EXECUTIVE FUNCTIONING

38

Stephanie Annies, M.D. M.Sc.

TMS for Executive Function Deficits in Autism Spectrum Disorder



39

TMS FOR EXECUTIVE FUNCTION DEFICITS IN AUTISM SPECTRUM DISORDER

- N=40 16-35 years old
- Double-blind, randomized, sham controlled trial
- 20 sessions, 4-week course of 20 Hz rTMS delivered to bilateral DLPFC (750 pulses per session at each hemisphere) at 90% resting motor threshold
- 95% of randomized patients completed the protocol
- No significant difference between active and sham
- Patients with lower baseline functioning experiences significant improvement with active TMS

Ameis SH, et al. Treatment of Executive Function Deficits in Autism Spectrum Disorder with Repetitive Transcranial Magnetic Stimulation: A Double-Blind, Sham-Controlled, Pilot Trial. Brain Stimulation. May-Jun 2020;13(3):539-547. doi: 10.1016/j.brs.2020.01.007. Epub 2020 Jan 15

40

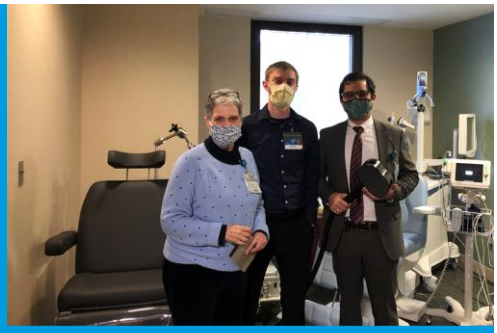
BILATERAL TRANSCRANIAL MAGNETIC STIMULATION OF THE SUPPLEMENTARY MOTOR AREA IN CHILDREN WITH TOURETTE SYNDROME

Cynthia Kahl

- Ten children with Tourtette syndrome (8 males) aged 9-15 years
- Eight of the subjects had comorbid ADHD
- Other comorbidities: OCD, epilepsy, anxiety, social phobia
- Medications continued (guanfacine, clonidine, ethosuximide, methylphenidate, fluoxetine, aripiprazole, risperidone, clomipramine, citalopram, amitriptyline, and fluphenazine)
- 15 sessions of neuronavigated, robotic 1 Hz rTMS at 100% motor threshold with 1800 pulses
- The Yale Global Tic Severity Scale decreased from baseline ($p < 0.001$, Cohen's d=2.9)
- Dominant motor cortex cortical silent period measures increased with treatment.

Kahl CK, et al. Bilateral transcranial magnetic stimulation of the supplementary motor area in children with Tourette Syndrome. Dev Med Child Neurol 2021 Feb 25. doi: 10.1111/dmcn.14828. Online ahead of print.

41



42

ACKNOWLEDGEMENTS

Collaborators:
Stephanie Ameis
Arjun Athreya
Daniel Blumberger
Doo-Sup Choi
Nancy Donachie
Jonathan Downar
Zafiris "Jeff" Daskalakis
Deniz Doruk-Camsari
Faranak Farzan
Parmis Fatih
Mark Frye
Juan Garzon
Marjorie Gresbrink
Utku Kucuker
Simon Kung
Joseph Kriske
Jarrod Leffler
Charles Lewis
Brian Lundstrom
Victoria Middleton
Can Ozger
Cinar Oztosun
John Port
Jennifer Rodger
Magdalena Romanowicz
Maria Saliba
Shirlene Sampson
Bhedita Seewoo
Julia Shekunov
Michelle Skime
Irem Sonmez
Cynthia Stoppel
Jennifer Vande Voort
Jeremy Weiss
Gregory Worrell
Deniz Yuruk
Michael Zaccariello

Mayo Clinic Division of Child and Adolescent Psychiatry and Psychology

Funding:
Brain and Behavior Research Foundation (NARSAD)
NIMH K23 MH100266
NIMH R01 MH113700
NIMH R01 MH124655
Mayo Clinic Foundation
Neuronetics
NeoSync
Pfizer, Inc

43