

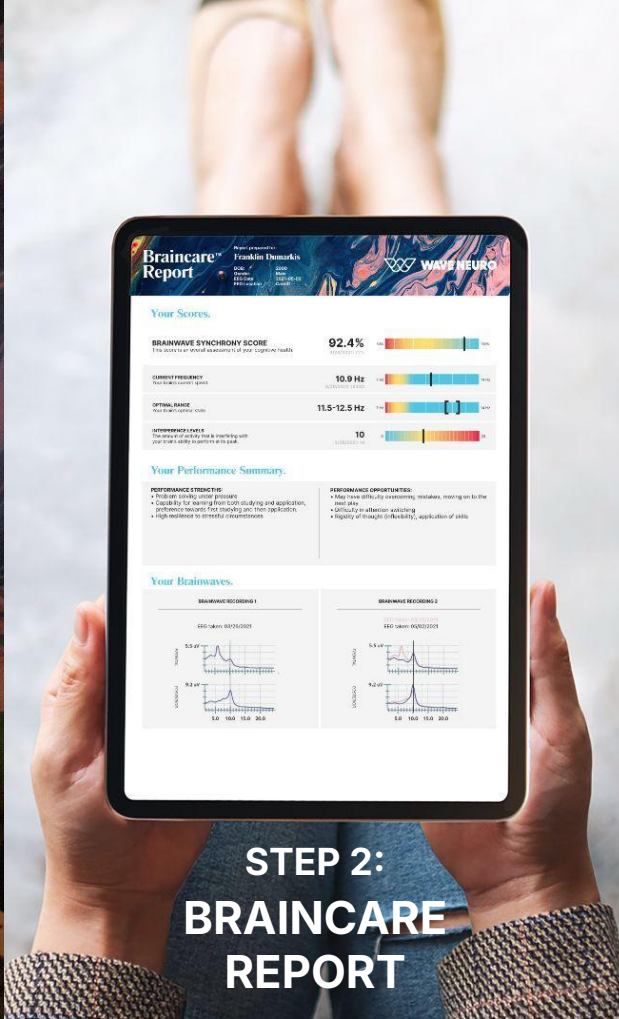


eTMS Update & Opioid Pilot Data

How it Works



STEP 1:
BRAINWAVE
RECORDING



STEP 2:
BRAINWAVE
REPORT



MERT
In-clinic therapy

STEP 3:
PERSONALIZED
NEUROMODULATION



November 11, 2024

Wave Neuroscience
Shahzaib Rai
Director QARA
1601 Dove St STE 205
Newport Beach, California 92660

Rc: Q241184/S001
Trade/Device Name: MRT-005 System
Received: September 12, 2024

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fo
We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device.

with Post-Traumatic Stress Disorder (PTSD), by reducing the severity of their symptom scores. We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at <https://www.fda.gov/media/162413/download>.

We recommend you review the FDA guidance document for the Breakthrough Devices Program referenced above for the available mechanisms for obtaining feedback from the Agency on device development for



Comparative Effectiveness

Reference	Standard of Care Treatment for PTSD	PCL-5 Mean Improvement
		Mean [sd] / %
Shiner et al., 2020	Antidepressants FDA cleared for PTSD:	
	Sertraline	7.5 [12.2] / 13.0%
	Paroxetine	6.8 [16.0] / 11.6%
DeGraba et al., 2021	National Intrepid Center of Excellence (NICOE) -Interdisciplinary Intensive Outpatient Program	8 / 16.0%
McGeary et al., 2022	Cognitive Behavioral Therapy (CBT) vs TPU	11.2 [2.2] / 23.5%
Cohen et al, 2004	rTMS RCT	31.2% (active)
		3% (sham)
Philip et al., 2019	sTMS RCT	28.1 % (active)
		21.2% (sham)
Ohio eTMS Program 2024	α-rTMS / MeRT	63.8%
IDE#G230168 FDA Trial	α-rTMS / MeRT	56.3%
Ohio eTMS Phase1 2024		
Taghva et al., 2015	α-rTMS / MeRT	42.1%

Medication
Management

Inpatient Program

Outpatient Program

Standard “One Size Fits All” Transcranial Magnetic Stimulation (TMS) for PTSD

eTMS (Personalized Protocols) for PTSD

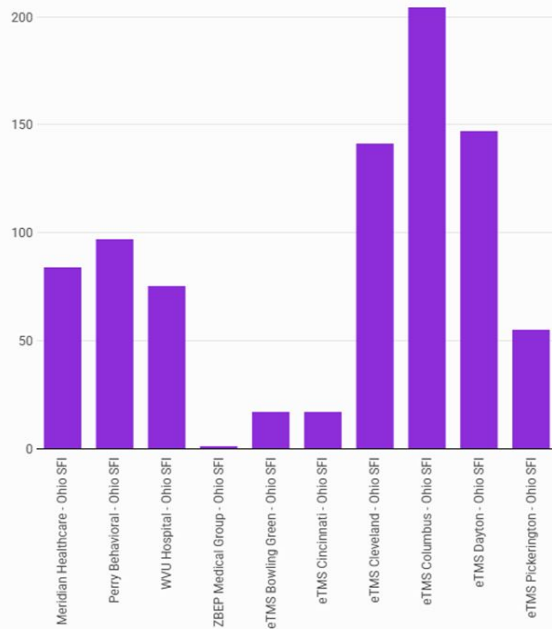


Patients
835

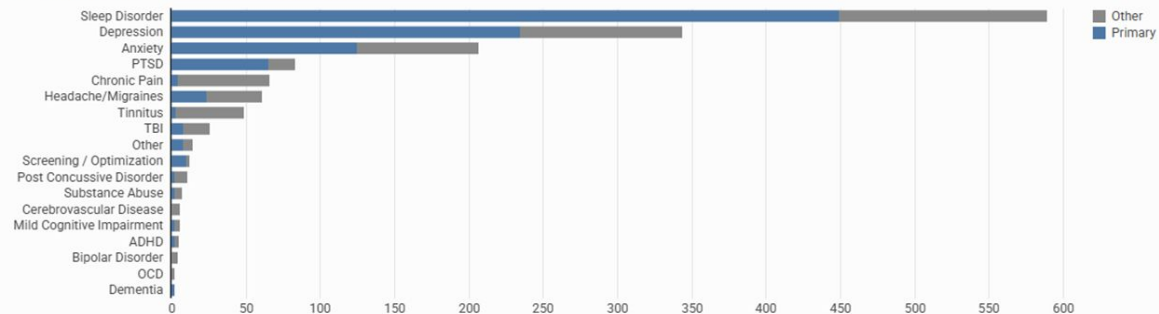
Scales
4,272

EEGs
2,699

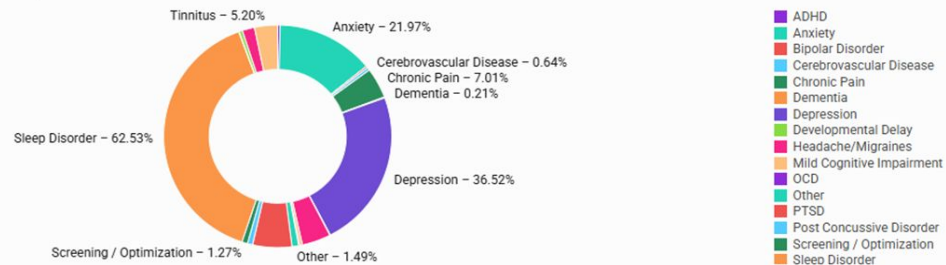
Patients by Clinic



Patient Breakdown by Chief Complaint



% of Patients by Chief Complaint



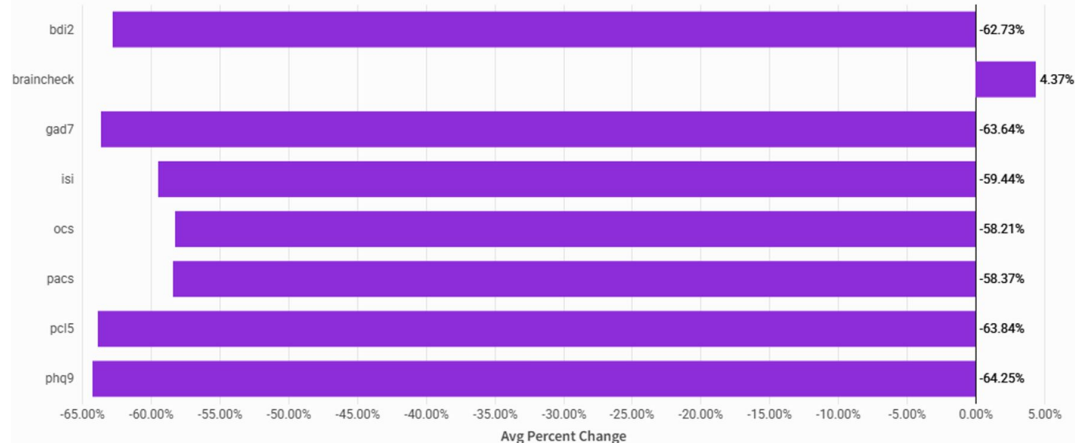
Scale Index:

Beck Depression Inventory (BDI2)
Braincheck (Neurocognitive Battery)
Generalized Anxiety Disorder-7 (GAD-7)
Insomnia Severity Index (ISI)
Opiate Craving Scale (OCS)
Penn Alcohol Craving Scale (PACS)
Post Traumatic Checklist DSM-V (PCL-5)
Personal Health Questionnaire 9 (PHQ-9)

Summary Table

Scale	Avg Initial Score	Avg Final Score	Avg Percent Change	n
bdi2	21.53	8.08	-62.46%	711
braincheck	98.26	102.56	4.38%	384
gad7	11.41	4.18	-63.41%	698
isi	15.72	6.4	-59.30%	709
ocs	5.58	2.33	-58.21%	24
pacs	7.25	3.05	-57.93%	474
pcl5	34.58	12.53	-63.76%	579
phq9	12.27	4.41	-64.04%	711

Average Percent Changes Since Initial



Ohio Substance Use Disorder Pilot:

In March of 2024, Ohio began a pilot project to explore the effects of eTMS (MeRT) on the substance use disorder population. Using eTMS in two inpatient residential treatment centers in Ohio, patients were given 20 sessions of eTMS in conjunction with behavioral therapy and traditional treatment.

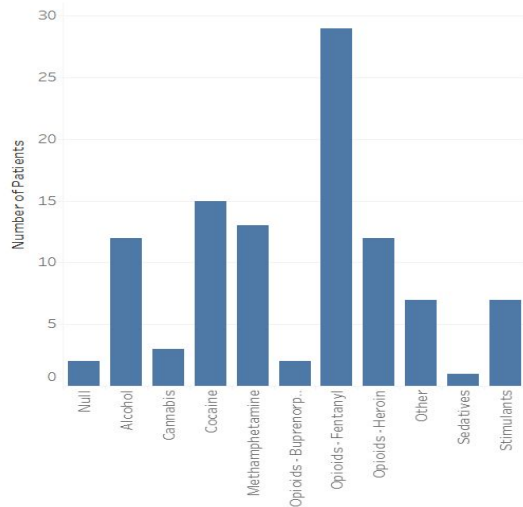
These are the results....

SUD Dashboard

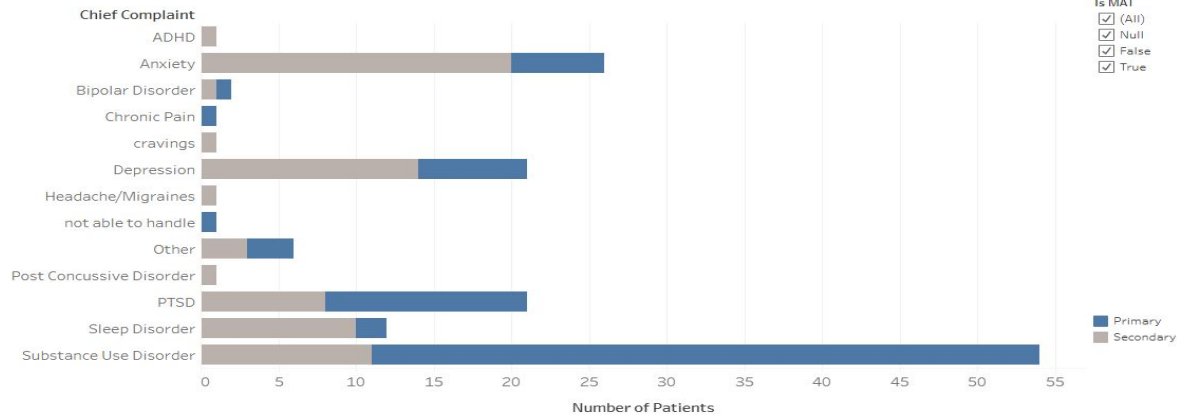
Patients Enrolled

141

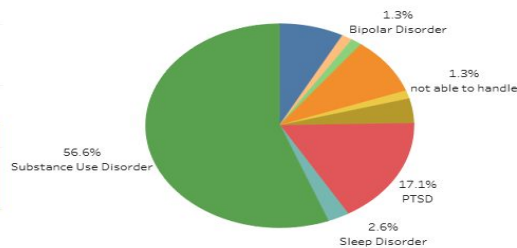
Drugs of Choice



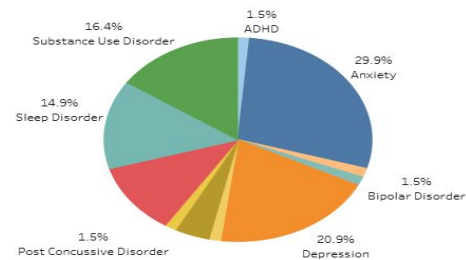
Patient Breakdown by Chief Complaint



Primary Complaints



Secondary Complaints



Property of JLC Services, Inc.

Baseline Date

2/2/2024

○

Is MAT

☒ (All)

☒ Null

☒ False

☒ True

■ Primary
■ Secondary

Scale Index:

AUDIT: Alcohol Use Disorders Identification Test

BDI-II: Beck Depression Inventory

BSC: Stimulant Brief Substance Craving Scale

DAST-10: Drug Abuse Screening Test

GAD-7: Generalized Anxiety Disorder-7

ISI: Insomnia Severity Index

OCS: Opioid Craving Scale

PACS: Penn Alcohol Craving Scale

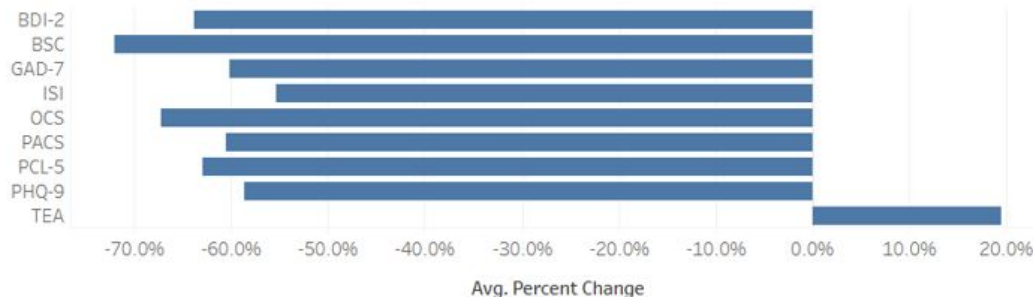
PCL-5: PTSD Checklist for DSM-5

PHQ-9: Patient Health Questionnaire

TEA: Treatment Effectiveness Assessment

	Avg. Baseline Score	Avg. Final Score	Avg. Percent Change	Avg. Score Change	n
BDI-2	28.7	10.3	-63.9%	-18.4	127
BSC	9.7	2.7	-72.1%	-7.6	124
GAD-7	13.4	5.4	-60.2%	-8.5	127
ISI	16.7	7.4	-55.4%	-8.6	119
OCS	11.0	3.6	-67.3%	-7.5	127
PACS	4.6	1.8	-60.6%	-2.7	120
PCL-5	40.6	15.1	-62.9%	-25.0	68
PHQ-9	14.9	6.2	-58.7%	-7.8	118
TEA	26.5	31.6	19.5%	5.8	105

% Change from Baseline



PTSD and SUD Case



Note: Jeff has provided consent to share his case

PTSD and SUD Case - Before Treatment



- Insomnia (“haven’t had a good night of sleep in 11 years”)
 - Medicates & drinks himself to sleep
- Chronic Pain
 - Failed back surgery x 2
 - 170 morphine equivalents daily
 - “Every antidepressant known to man”
 - 20 pills/day (antidepressants, muscle relaxants, pain pills, etc)
- Utilized every available VA treatment modality for PTSD
- Anger issues, road rage, hypervigilance in crowds, depressed mood, etc.



PTSD Case – After Treatment

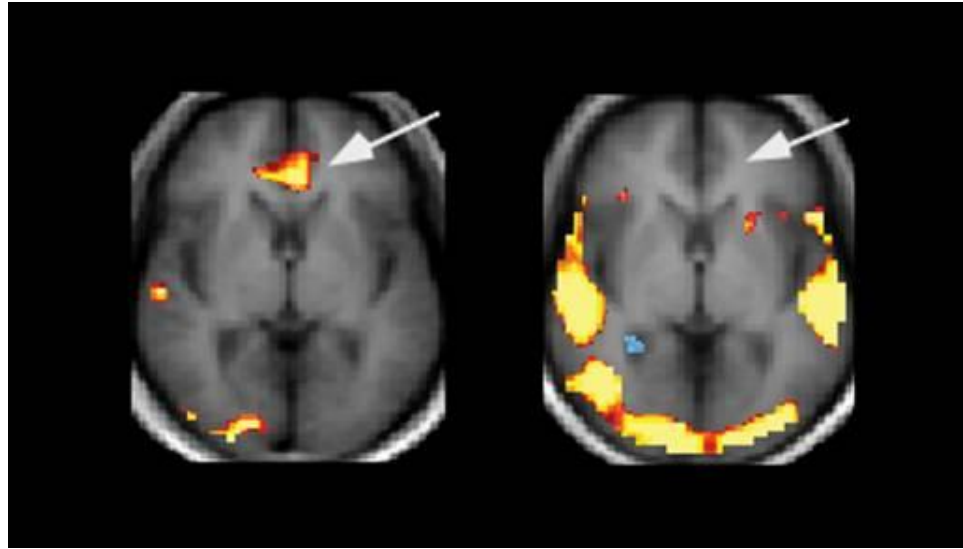


- After six weeks of treatment...
- “Best sleep I’ve had in years”
- Anger dissipated
- Upbeat mood
- Chronic pain dramatically reduced (hyperalgesia resolved)
 - Off all prescription drugs
 - Takes 1 pills/day (Vitamin D)
- Completed a Masters of Social Works (Addiction Counseling)
- Now enrolled in Masters of Business Administration



Functional MRI (f-MRI) and Addiction

- Morphologic changes of the addicted brain are observable

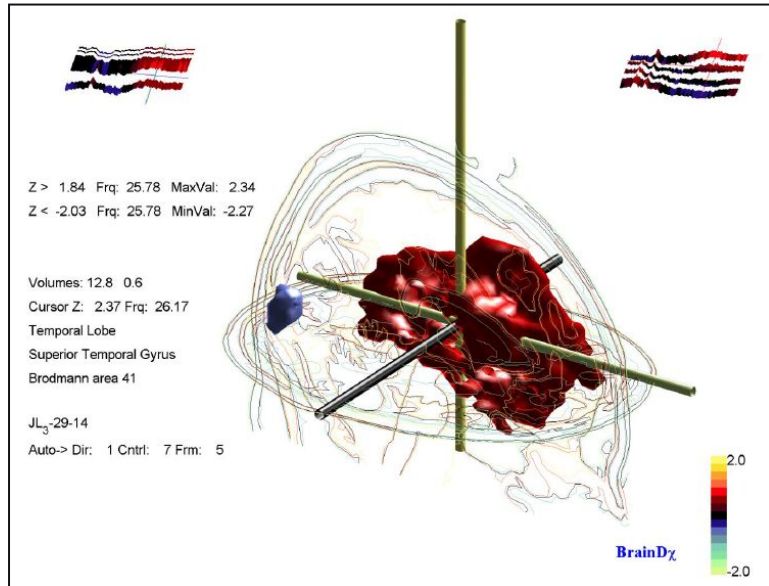


f-MRI The brains response to cocaine. Arrows point to the anterior cingulate area, which is activated in cocaine addicted patients (left) but not in healthy volunteers (right) (Wexler, et al. 2001)

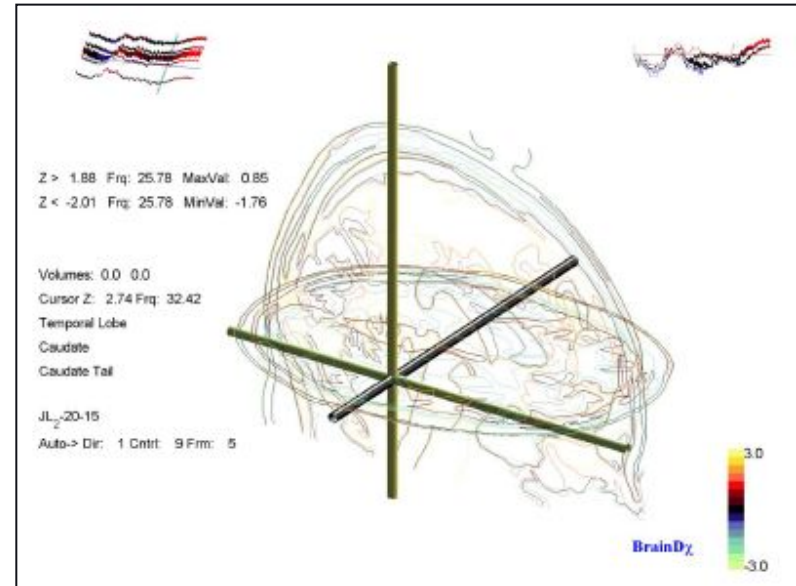


Quantitative EEG

Pre Treatment



Post Treatment



Ohio State Bill 153 (SB 153) ☐ HB110 (Appropriation)



As Passed by the Senate

134th General Assembly
Regular Session
2021-2022

Am. S. B. No. 153

Senator Hoagland

Cosponsors: Senators Antonio, Blessing, Cirino, Craig, Dolan, Fedor, Gavarone, Hackett, Hottinger, Huffman, S., Johnson, Kunze, Lang, Maharath, Manning, McColley, O'Brien, Peterson, Reineke, Romanchuk, Rulli, Schaffer, Schuring, Thomas, Williams, Wilson, Yuko

A BILL

To amend section 5902.09 of the Revised Code to	1
expand the Electroencephalogram (EEG)	2
Transcranial Magnetic Stimulation (TMS) Pilot	3
Program and to make an appropriation.	4

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That section 5902.09 of the Revised Code be	5
amended to read as follows:	6