

Bringing Breakthrough Brain Science to Help America's Returning Warriors, Veterans and the Rest of Us

Newport Brain Research Laboratory
Brain Treatment Center



Newport Brain Research Laboratory/Brain Treatment Center Mission Statement

Newport Brain Research Laboratory (NBRL) is a life science company focused on technology in brain science. NBRL has the capability to uniquely image the brain, identify areas of the brain that are not functioning properly and, most importantly, restore the problematic regions of the brain to optimal neurological function using non-invasive neuromodulation.



Strategic Partnerships

Keck Medical
Center of USC
Center for Neurorestoration



St. Joseph Hoag Health
Hoag • Mission • St. Joseph • St. Jude
In alliance with CHOC Children's

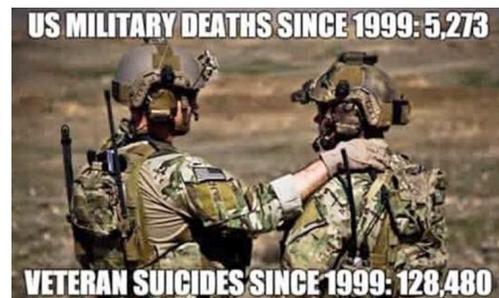


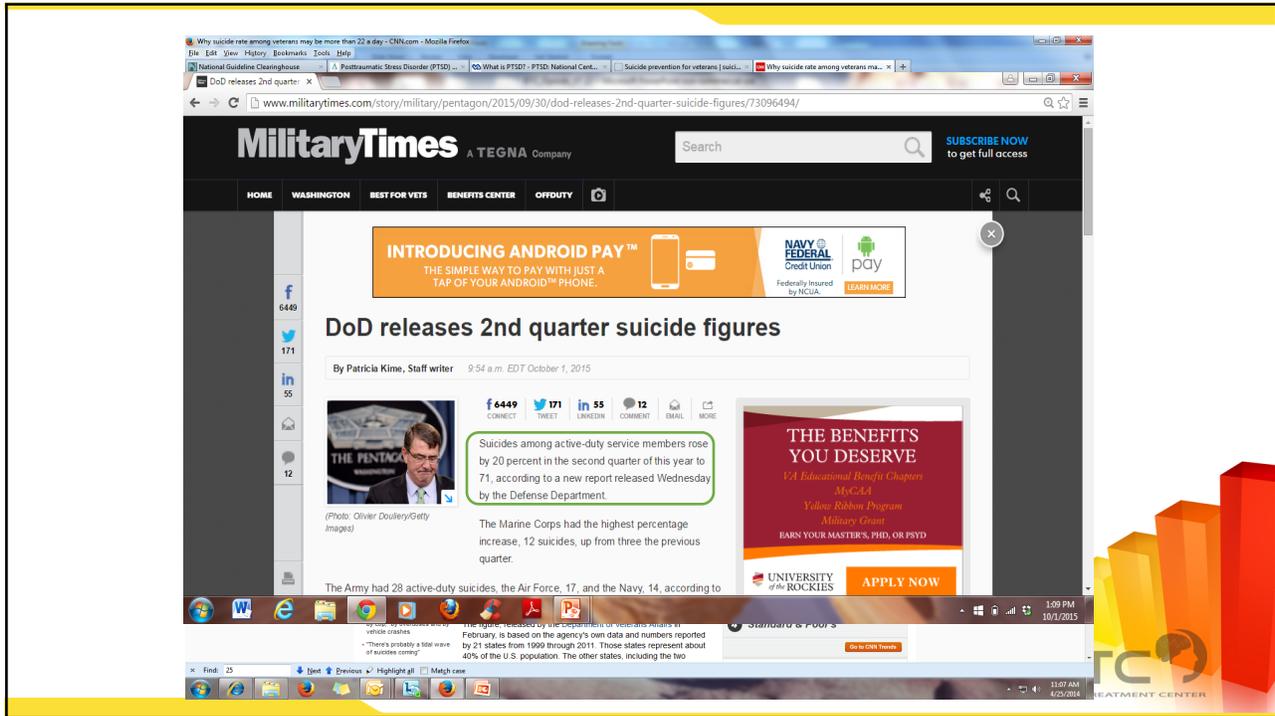
Rancho Los Amigos National Rehabilitation



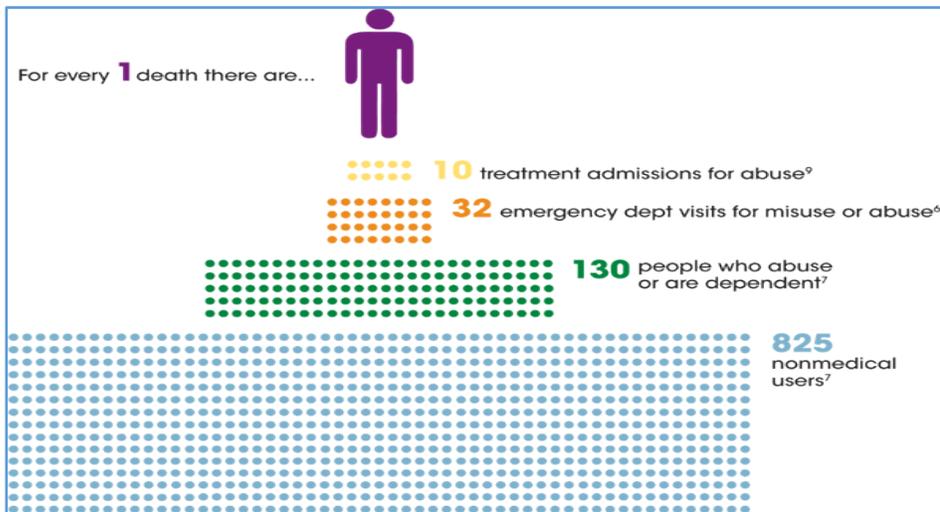
Scope of the Problem

- TBI called the “signature injury” of OEF/OIF
 - 33% of all patients and 60% of patients with blast related injuries seen at Walter Reed had TBI (Okie, 2005)
 - Veterans Health Initiative Traumatic Brain Injury
- 13.8% of Gulf War Vets suffer from PTSD
 - 50% do not seek treatment, of the half that do only 25% get “minimally adequate” treatment
 - Rand, Center for Military Health Policy Research
- 22 suicides/day among US Military Veterans, more active duty personnel die by their own hand than combat in 2012
 - Department of Veterans Affairs, Mental Health Services





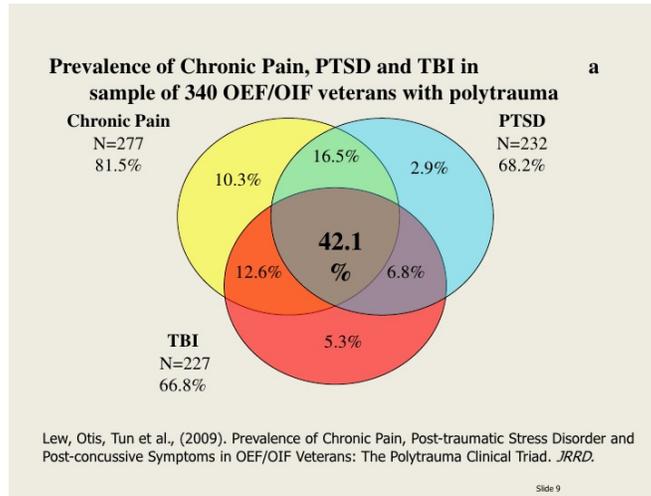
Mortality = "Tip of the iceberg"



Source: CDC - Injury Prevention & Control – Prescription Pain Killer Overdoses
<http://www.cdc.gov/homeandrecreationalafety/rxbrief/>



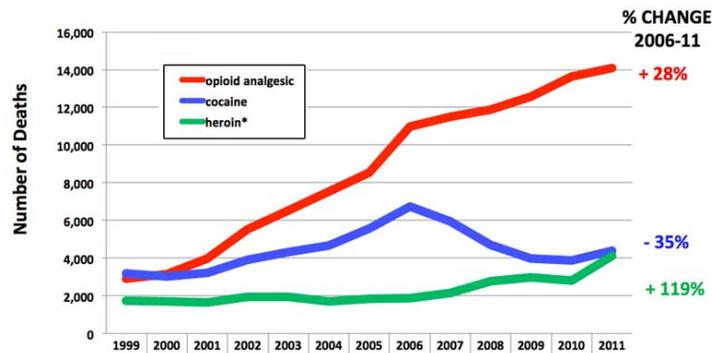
VA Polytrauma Model



Chronic Pain and Opioids

More physician prescribed opioid fatalities than illicit cocaine and heroin combined

Unintentional Drug Poisoning Deaths Involving Opioid Analgesics, Cocaine and Heroin: United States, 1999–2011



Neuromodulation

- Neuromodulation – Refers to an emerging class of medical therapies that target the nervous system for restoration of function, relief of pain, and/or to control symptoms of depression/anxiety.
 - Invasive Neuromodulation
 - Non-Invasive Neuromodulation

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Neuromodulation (Invasive)

- Surgical (Invasive) Neuromodulation, called Deep Brain Stimulation (DBS), has been a rapidly evolving area of neurosurgical intervention and is now considered “standard of care” for drug resistant Parkinson’s and OCD.

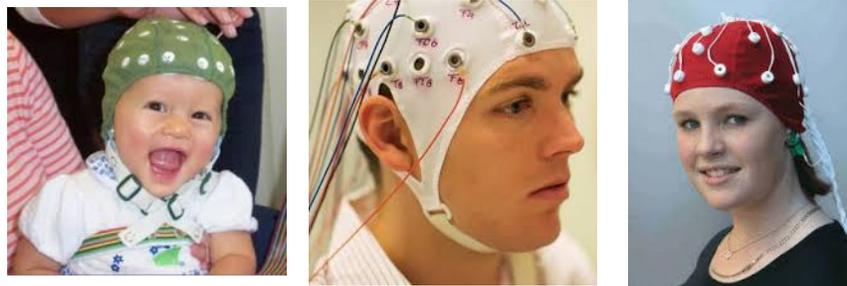


Neuromodulation (Non-Invasive)

- **Despite good outcomes with DBS, patients have been largely unwilling to undergo brain surgery with craniotomies.**
 - Less than 30% of candidates eligible for DBS surgery agree to have it performed.
- >> **Race to develop a “non-invasive” neuromodulation modality!**
 - **Repetitive Transcranial Magnetic Stimulation (rTMS)**
 - Magnetic energy directed to the left dorsolateral prefrontal cortex (10 Hertz at 120%)
 - FDA approved for treatment of depression in 2008, now widely available.
 - **Magnetic e-Resonance Therapy (MeRT) technology**
 - Customized application of rTMS treatment: Guided by brain map (q-EEG), personalized, precision, prime frequency (.00 Hertz) at 60-80% of threshold.
 - Early Data: Almost twice as effective as rTMS in head-to-head clinical trials.
 - Much broader application than just depression: Autism Spectrum Disorder (ASD), PTSD, Depression/Anxiety, and Addiction/Substance Use Disorder.



Quantitative EEG (q-EEG)

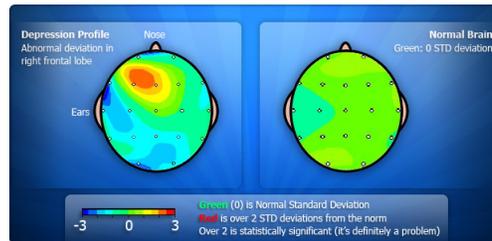


q-EEG is painless and takes only 20-30 minutes



Quantitative EEG - Concepts

- Measures six brainwave clinical bands
- Every individual has a “cognitive fingerprint” with an intrinsic wavelength profile...deficits can be picked up when an area of the brain deviates from the intrinsic wave signature

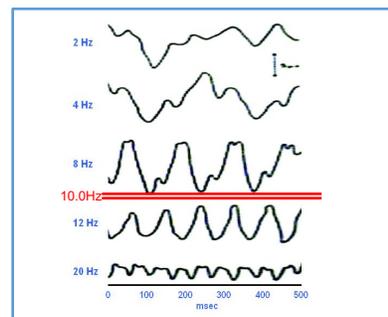
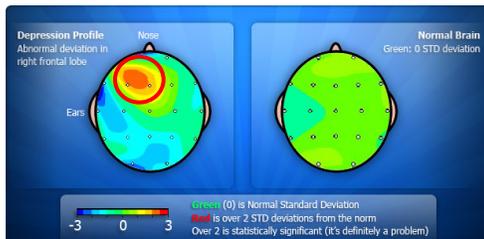


Major depression manifests as abnormality of the left dorsolateral prefrontal cortex (DLPFC).



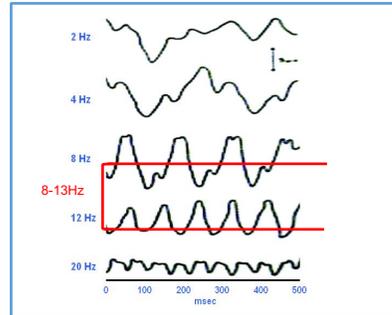
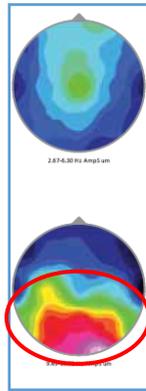
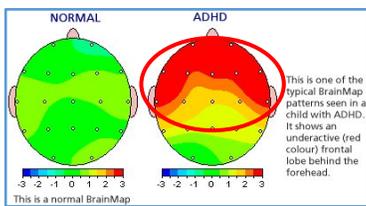
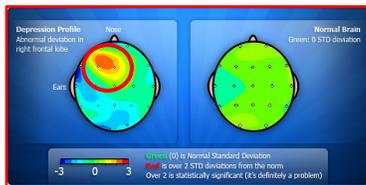
Repetitive Transcranial Magnetic Stimulation (rTMS)

- FDA approved treatment for drug-resistant major depression (2008)
 - 1st Generation – Transcranial Magnetic Stimulation (TMS)
 - Alpha wave fixed at 10.0 Hz via single coil device delivered to the LDLPFC = 33% response rate for drug-resistant depression



Magnetic e-Resonance Therapy (MeRT)

- 2nd Generation – Magnetic e-Resonance Therapy (MeRT)
 - MeRT (deep signal) across multiple bands, personalized to an individuals intrinsic profile, and guided by q-EEG to specifically targeted areas (brain navigation)



PTSD

Neuromodulation (Non-Invasive)



Non-pharmaceutical (no systemic side effects), non-invasive (painless), similar exposure to a standard MRI (almost no adverse events), with strong clinical efficacy



Neuromodulation (Non-Invasive) Adverse Effects

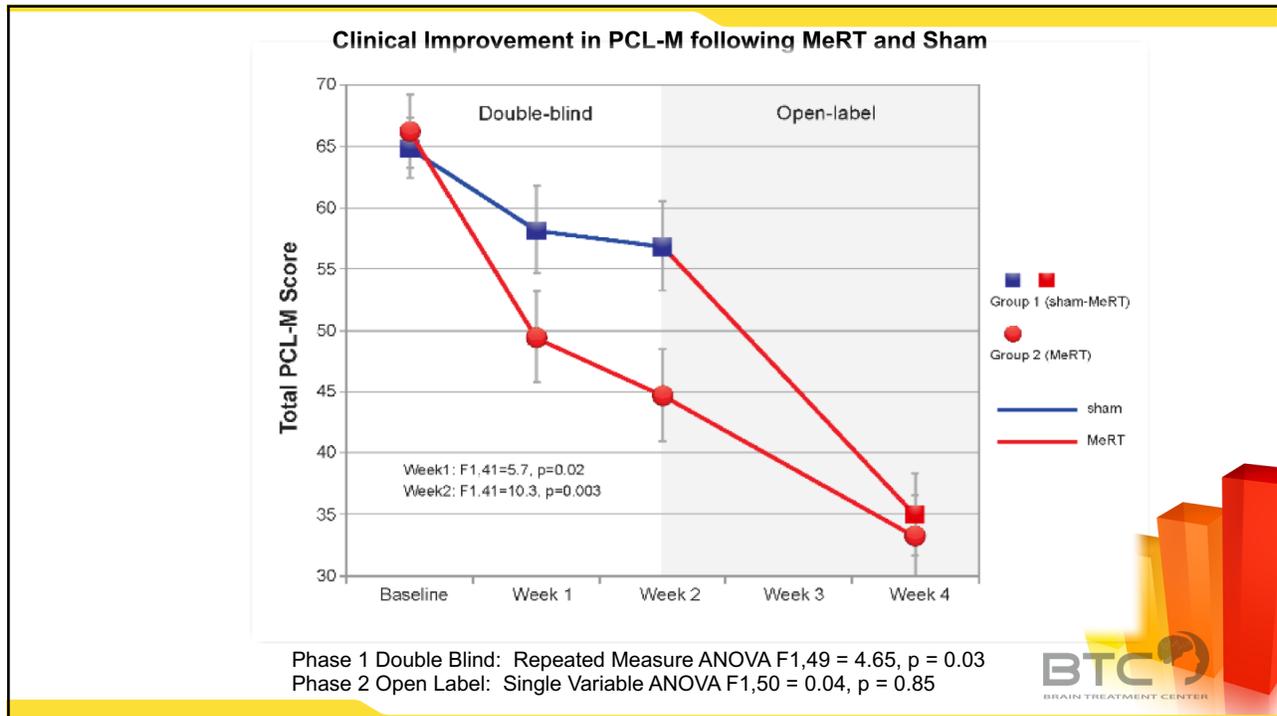
- Temporary discomfort/pain at scalp
- Temporary headache
- Overstimulation (excitation)
- Seizure (estimate 1:100,000 – 1:500,000)
(Note: Nintendo warns of 1:4000 seizure possibility)



PTSD – Prospective, Double Blind, Placebo- Controlled, Randomized Controlled Trial

- 86 subjects (77 M & 8 F) / Average Age 37.8 yrs / Moderate-Severe PTSD
- Phase 1: patients randomly assigned into one of two treatment groups - Active MeRT Treatment or SHAM (Placebo Control) Treatment - for two weeks. Technicians delivering treatment were blinded.
- Severity of clinical symptoms was evaluated using quantitative rating scale - PTSD Checklist Military (PCL-M) - by a research clinician who was blinded to the treatment condition.
 - PCL-M: a well-recognized and validated questionnaire scoring range 0-80
 - Symptoms at baseline varied from 'moderate' to 'severe' (38-80)
- Phase 2: two-week, Open-Label Trial during which all received active MeRT treatment.

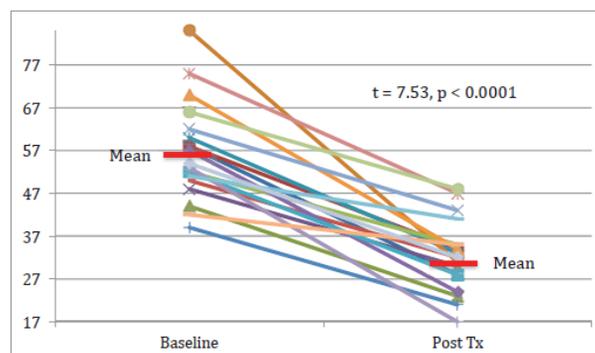




Neuromodulation (Non-Invasive) MeRT Studies - PTSD

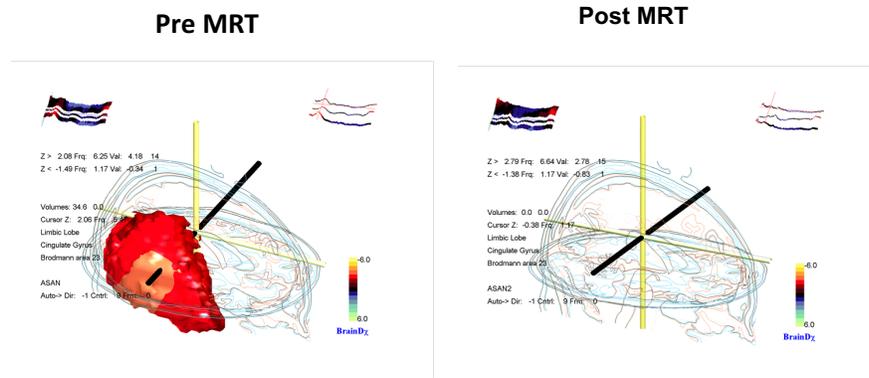
- Average 63% reduction in symptom severity (Fig.1; $p < 0.0001$).
- Accordingly, patients demonstrated EEG improvement in alpha power, coherence, and reduction in slow waves.

Figure 1. PCL-M change after MRT



Neuromodulation (Non-Invasive) MeRT Studies – TBI/PTSD

- Corroboration of PCL-M scores (subjective questionnaire) with q-EEG brain imaging (objective study)



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A Case . . .



Note: Jeff has provided consent to share his case

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Before Treatment . . .



- Insomnia -*"I 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
 - 20 pills/day (antidepressants, muscle relaxants, pain pills, etc)
 - *"Every antidepressant known to man . . ."*
- Utilized every available VA treatment modality for PTSD and addiction.
- Anger issues, road rage, hypervigilance in crowds, depressed mood, etc.



After Treatment . . .



After 6 weeks of MeRT treatment:

- Restful sleep
- Anger dissipated
- Upbeat mood
- Chronic pain dramatically reduced (hyperalgesia resolved)
 - **Off all prescription drugs**
 - **Takes 1 pill/day (Vitamin D)**
- Completed a Masters of Social Works (Addiction Counseling)
- Applying for PhD programs





Chronic Pain and Brain Function NIH Funded Study

- An NIH sponsored study utilizing f-MRI and diffusion tensor imaging (DTI) identified areas of the brain that may predispose individuals to chronic pain. The results, published in the journal *Pain*, support the growing idea that the brain plays a critical role in chronic pain.
- “We may have found an anatomical marker for chronic pain in the brain...Our results suggest that the structure of a person’s brain may predispose one to chronic pain. We were surprised how robust the results were and amazed at how well the brain scans predicted persistence of low back pain,”
 - Vania Apkarian, Ph.D., senior author of the study and professor of physiology at Northwestern University Feinberg School of Medicine

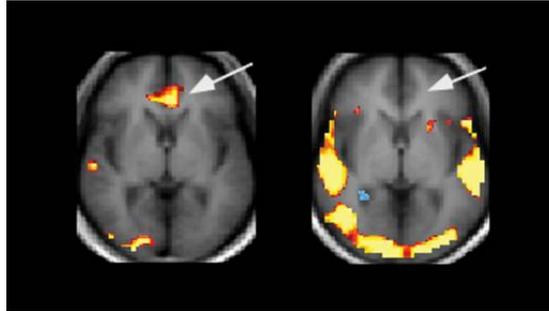
Brain white matter structural properties predict transition to chronic pain. Mansour AR, Baliki MN, Huang L, Torbey S, Herrmann KM, Schnitzer TJ, Apkarian AV. *Pain* - Sept 2013.

<http://www.nih.gov/news/health/sep2013/ninds-17.htm>



Functional MRI (f-MRI) and Addiction

- Morphologic changes of the addicted brain are observable



f-MRI The brain's 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)

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MeRT Trial 002 - PTSD

Findings from PTSD study...

- 63% reduction in symptom severity (PCL-M).
- 96% reported improved quality of sleep.
- VAS Pain Scores reduced from 7.4 to 2.7.
- **25% voluntarily weaned off opioids**
- **86% of Veterans voluntarily decreased opioid use.**
- **77% of Veterans voluntarily decreased alcohol use.**

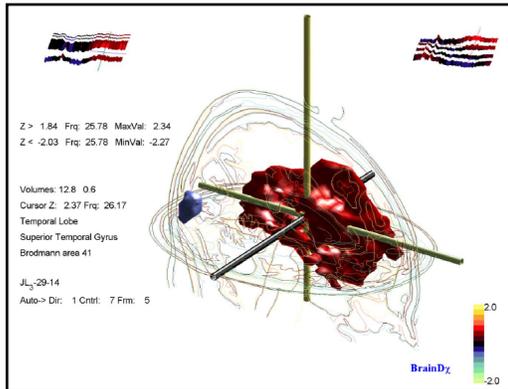
*Data points still holding at 1-year marker . . .

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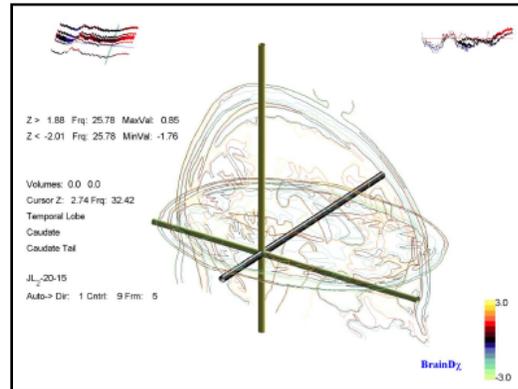


Quantitative EEG

Pre Treatment



Post Treatment



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“All truth passes through three stages.
 First, it is ridiculed. Second, it is
 violently opposed. Third, it is accepted
 as being self-evident”

--

Arthur Schopenhauer, German Philosopher
 (1788-1860)


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So . . . Where are we with all of this?



Department of Defense

- Tinker Airforce Base . . .
 - Randomized, Double-Blind, Placebo-Controlled Trial Underway
- US Special Operations Command . . .
 - Two-Site Trial (CA and FL) being mounted by Uniformed Services for Health Sciences (USUHS)

"The USSOCOM Command Surgeon and several senior members of the Special Operations Community have witnessed some remarkable anecdotal results from the treatment provided by NBRL; some of which defy traditional medical explanation. We are excited about the opportunity to further explore this method of treatment to help our active duty and veteran teammates in DOD."

CAPT (SEAL) J Doolittle, USN, Director, Preservation of the Force and Family (POTFF)



FY2017 Military Construction, Veterans Affairs and Related Agencies Appropriations Bill Conference Report

(Report 114-640) Page 88:

New research areas. — As indicated in the House report, the conferees encourage VA to create a Center of Innovation for research support and use as candidates for initial research hyperbaric oxygen therapy and Magnetic EEG/EKG-guided Resonance Therapy.



114TH CONGRESS 2D SESSION

JUNE 28, 2016 . . . Introduced in the HOUSE
“No Hero Left Untreated Act” HR 5600

To direct the Secretary of Veterans Affairs to carry out a pilot program to provide access to magnetic EEG/EKG-guided resonance therapy technology to veterans.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the **“No Hero Left Untreated Act”**.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Magnetic EEG/EKG-guided Resonance Therapy technology (in this section referred to as “MeRT technology”) has successfully treated more than 400 veterans with post-traumatic stress disorder, traumatic brain injury, military sexual trauma, chronic pain, and opiate addiction

**9/21 - PASSED THROUGH FULL COMMITTEE MARK-UP AND REPORTED FAVORABLY TO THE HOUSE
 FLOOR VOTE EXPECTED DURING THE LAME DUCK SESSION**

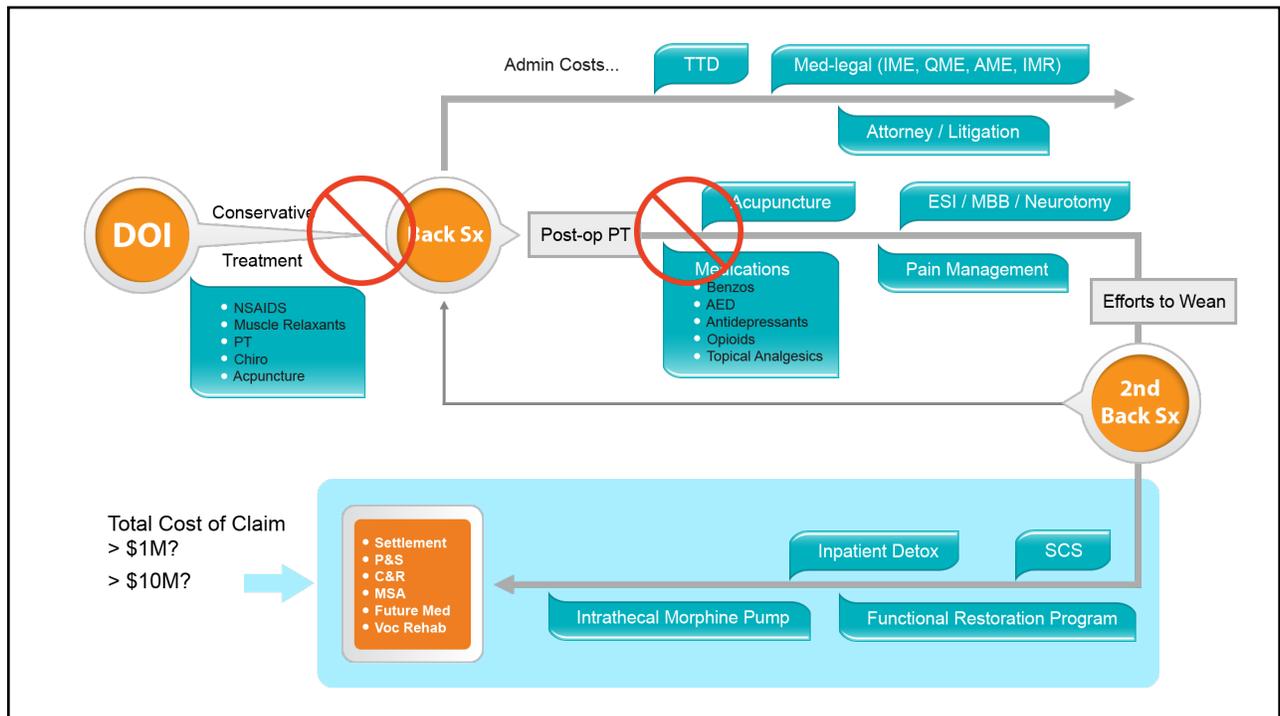


Private Insurance Pilot Data

- Based on Veteran results, a pilot was conducted through Workers Compensation to assess efficacy for injured workers with chronic pain and opioid dependence:
 - All subjects reduced opioid dose by 50% within the first month.
 - Sixty-six percent (66%) successfully weaned off opioids.
 - The remaining third (33%) were able to reduce to a safer, low dose, opioid regimen.
 - One case went from 700 morphine equivalents daily (MED) to 80 MED's
 This patient felt well enough to find a new job and return to work after **18 years** of “total disability” and unemployment.
 - Subjects reported “very limited” or “no withdrawals” . . . the weaning process characterized as a “soft landing.”



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MeRT Summary

- MeRT is an innovative medical technology demonstrating strong clinical efficacy for opioid dependence.
 - Clinical efficacy is corroborated by post-treatment brain imaging.
- MeRT has an excellent safety profile.
 - Non-invasive, minimal side effects or adverse events, in an outpatient setting with the same exposure/energy of an MRI.
- MeRT is cost effective.
 - A fraction of the cost of lifetime opioid treatment
- MeRT transforms Quality of Life factors.
 - Impossible to quantify the impact . . . Patients (and family members) identify transformative quality of life changes!

