

CRANIAL ELECTROTHERAPY STIMULATION

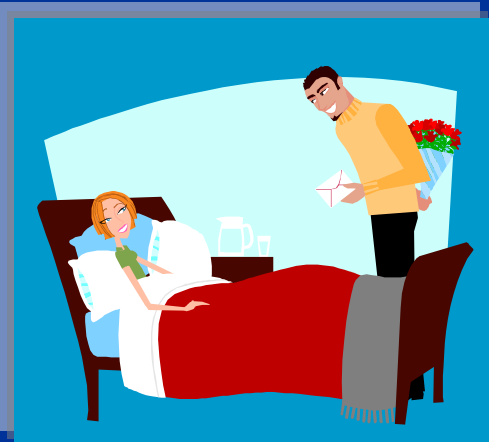


**GATEWAY TO RELIEF AND SYMPTOM REDUCTION IN
THE TREATMENT OF ANXIETY DISORDERS, DEPRESSIVE
DISORDERS, CHRONIC PAIN, AND SLEEP DISORDERS**

COL Kathy Platoni, Psy.D.

**Former Deputy Commander for Clinical Services;
Officer in Charge of Team Ar Ramadi,
Al Anbar Province,
Operation Iraqi Freedom
55th Medical Company
(Combat Stress Control)
October 2004 - December 2005**

.....
**Chief of Mental Health, 307th Medical Group
US Army Reserves**





Cranial Electrotherapy Stimulation

- n Serving the nation's finest and bravest
- n Breaking new ground in civilian practice



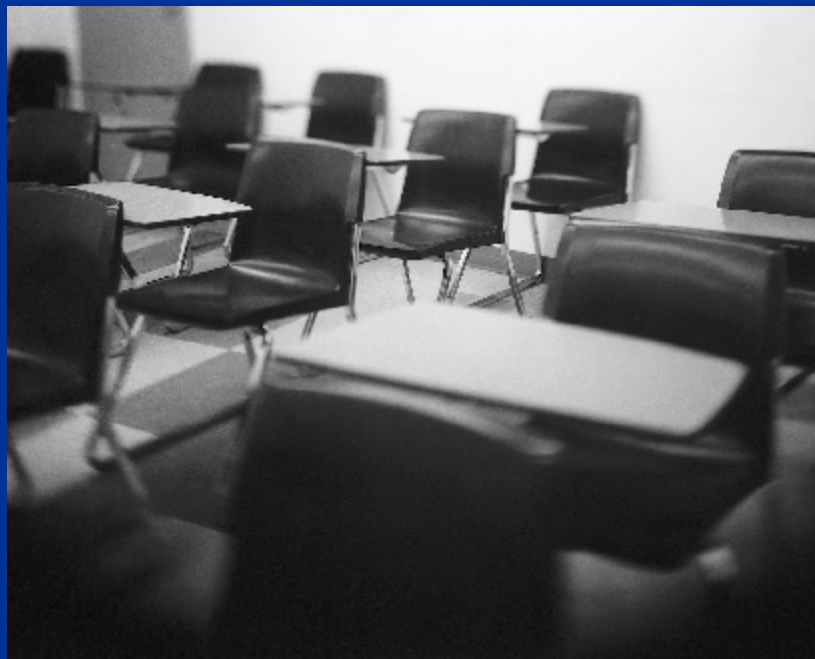


CES EXPERIENTIALLY

- n 16 years of experience in the treatment of chronic and intractable pain at Miami Valley Hospital, St. Elizabeth's Regional Pain Program, and private practice specializing in the treatment of chronic pain, depressive and anxiety disorders**
- n 2 years experience in the treatment of PTSD and other anxiety disorders in the wartime theater and with OIF veterans**
- n No disclaimers – no receipt of monetary compensation or remuneration from industry**
- n Through valiant and undying efforts on the part of EPI, Inc. and relentless battles in court and over phone and fax, the majority of my caseload now owns their own Alpha-Stim SCS devices, whether on State or Federal Workers' Compensation or private insurance**
- n Even those with fixed and very limited incomes have purchased refurbished devices, though numerous devices have been generously donated to patients by EPI (civilian and military)**

LESSONS LEARNED

- n PATIENT, SOLDIER, AND MARINE SELF-REPORTS
- n CASE STUDIES ON BOTH ACCOUNTS



SIDE EFFECTS AND CONTRAINDICATIONS?



- n Negligible reported negative side effects within all cases, even with a duration of up to 8 hours, other than brief tingling sensations in one or both ears that ceases within seconds and very occasional and brief episodes of lightheadedness and dizziness
(no more than 4 instances of this)**
- n CES has proven more effective than anti-anxiety, sedative-hypnotic, and antidepressant medications per patient self-reports**
- n In many instances, CES has been far more effective than narcotic analgesics per patient self-reports**

SURVEY OF SUBJECTIVE OUTCOME RATINGS FOR CRANIAL ELECTROTHERAPY STIMULATION APRIL – JULY 2007

CONDITION	N	WORSE	NO CHANGE	SLIGHT <24%	FAIR 25-49%	MODERATE 50-74%	MARKED 75-99%	COMPLETE 100%	SIG >25%
PAIN	14	0	4	3	1	4	1	1	50%
ANXIETY	8	0	0	0	3	3	2	0	100%
DEPRESSION	14	0	1	2	2	5	4	0	79%
SLEEP DISORDERS	13	1	2	0	2	4	3	1	77%
HEADACHE	1	0	1	0	0	0	0	0	0%

N=20

UNRATED DUE TO PATIENT UNAVAILABILITY OR NONCOMPLIANCE = 3

THE REST OF THE STORY

What cannot be quantified or drawn from data collected is considered “self-report” information, which cannot be overlooked in assessing outcomes.



SELF-REPORT DATA

(OR WHAT STATISTICS FAIL TO REVEAL)

n Patient # 1:

Diagnosis: Social Phobia (Anxiety Disorder)

Reported Outcomes: Patient now capable of training other residents under her supervision and to educate and inform attending staff without panicking and/or inability to recall vital educational material

n Patient # 2:

Diagnosis: PTSD

Reported Outcomes: Patient, with a 39 year history of PTSD, now able to stay awake for most of the day without being excessively sedated, is able to carry on coherent conversations, to process, store, and retrieve information; to drive a vehicle, to interact with family, friends, and health care providers, and to sleep through the night without horrific nightmares more than 30% of the time. Flashbacks are now limited to holidays (4th of July).



n Patient # 5:

Diagnoses: Major Depressive Disorder

Paranoid Delusional Disorder

Reported Outcomes: Patient is no longer mute, is now conversant, interacts socially, attends church, no longer paces the floor in highly agitated states, exercises 3 to 4 times weekly, and drives to his psychotherapy sessions. He was previously sufficiently impaired to be viewed as catatonic by the untrained eye, but was depressed to the point of immobilization. In the words of his spouse, he is once again approximating the husband she lost after years of overmedication and medication combinations that left him in a state described as “stuporous”, nonfunctional, and unable to relate to the rest of his world.

As soon as he stopped using CES for a period of 4 weeks for unknown reasons, his symptoms returned full force.

n **Patient # 7**

Diagnosis: Major Depressive Disorder
Pain Disorder Secondary to General
Medical Conditions (industrial injuries,
Fibromyalgia, and Multiple Sclerosis)

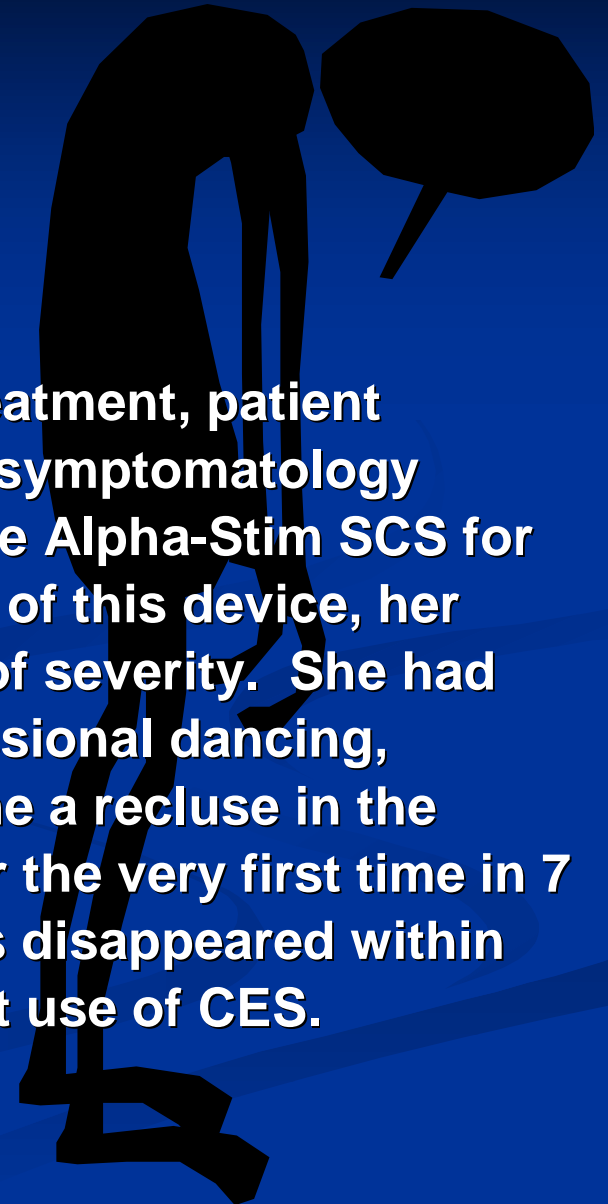


Reported Outcomes: Patient has experienced a 70% overall improvement in her daily functioning, including normalization of mood states, sleep cycles, energy level, ADL's, and a reduction in chronic, intractable pain sensations from 9 -10 on a VAS to 5 for hip pain and 3 for LBP. She reports her quality of life as having improved 90%. She is no longer taking any medications for the treatment of her MS, no longer relies on any pain medications with very rare exceptions due to infrequent flare-ups, is able to sleep through the night uninterrupted, and has the desire to interact with friends and family for the first time in 15 years. Complete pain relief is experienced within less than 20 minutes. Her scores on the Beck Depression Inventory now fall within the normal range, suggestive of "normal ups and downs".

n Patient # 8

**Diagnoses: Major Depressive Disorder
Pain Disorder Secondary to
General Medical Conditions**

Reported Outcomes: After her first CES treatment, patient reported a marked reduction in depressive symptomatology almost immediately and with daily use of the Alpha-Stim SCS for one week. Directly after stopping daily use of this device, her symptoms returned to their previous level of severity. She had literally lost the will to live, given up professional dancing, avoided all contact with friends, and become a recluse in the process. Suicidal feelings were reported for the very first time in 7 years. All of these self-reported symptoms disappeared within less than 48 hours of initial and subsequent use of CES.



n **Patient # 10**

Diagnoses: Major Depressive Disorder

Pain Disorder Secondary to General

Medical Conditions:

Fibromyalgia, Chronic Asthma



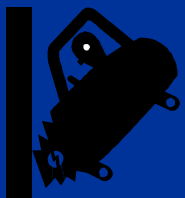
Reported Outcomes: Unexpectedly, this patient reported a 75% improvement in visual acuity and clarity, a 100% reduction in chronic and intractable pain, a complete cessation of migraine headaches, and a 50% reduction in symptoms of both depression and anxiety. Her overall level of energy and quality of life have improved by 50%. Over the course of her entire life, she had been perceived as a “sickly” individual with the weakest of constitutions. In her estimation, CES has provided her a life she never believed that she could have. Her healthcare providers are equally amazed at her progress.

n Patient # 11

**Diagnoses: Panic Disorder without Agoraphobia
Pain Disorder Secondary to General
Medical Conditions
Sleep Disorder**



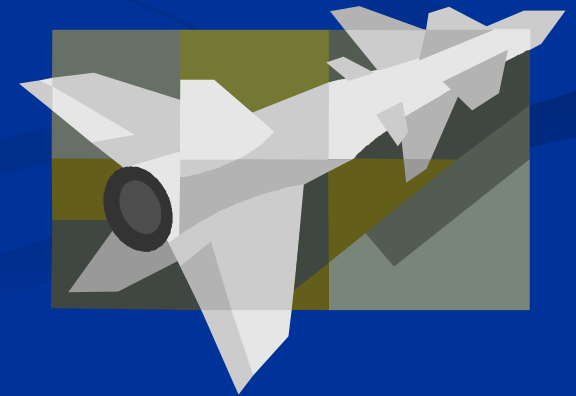
Reported Outcomes: Surprisingly, this patient indicated that her anxiety has diminished by 80%, that her sleep disorder had completely resolved, and that her pain has become tolerable for the very first time in more than 15 years. This patient had previously been unable to move through her days without continues panic episodes and severe anxiety that plagued many of her waking hours. On the State Trait Anxiety Inventory (STAI), her responses reflected no more than moderate levels of anxiety since initiating CES treatment in late 2006. Interestingly enough, her notable progress is in spite of a very poor internal locus of control and equally inadequate treatment compliance.



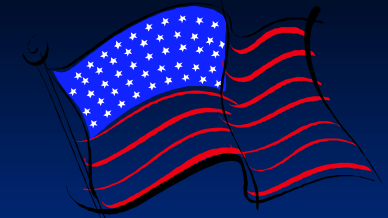
n Patient # 19

**Diagnoses: PTSD (Vietnam, Desert Storm, Somalia, and OIF)
Multiple Orthopedic and Shrapnel Injuries,
Kidney Disease (Service-Connected)**

Reported Outcomes: Patient's life has been altered remarkably by daily or twice daily use of CES: he can sleep for more than 2 consecutive hours without unintentionally assaulting his wife during hours of sleep (nightmares have decreased markedly), chronic pain has been reduced from agonizing to tolerable, and PTSD symptoms have eased to the degree that each hour of each passing day is not marked by relentless flashbacks and hypervigilance.



Patient Testimonial for PTSD Treatment with CES



“The Alpha-Stim has been the only thing that has really worked for me and worked consistently, without my being drugged up. The first noticeable affect is I could sleep, and sleep almost uninterrupted. It has been years since I could do that. Although I notice an increase in the vivid nature of my dreams and flashbacks it is strange that the affects of the AS unit, along with your counseling, are that I can recall events that have haunted me more clearly. This I feel has allowed me to emotionally express the feelings and difficulties I have dealing with my PTSD. I couldn't do that previously. Prior to this type of treatment, the bits and flashes of memory were just that, mostly indiscernible and often unidentifiable. That is why I have sought so long and hard to put my combat experiences back together. Once I was able to do this I think it reduced my anxiety. It doesn't go away, but at least I know where it is coming from, and as a result I feel I am better able to deal with it. With respect to hypervigilance I do not think for me that will ever go away. It is conditioned into me from years of experience and the number of traumatic events I have had to deal with. The reality is there are few safe places for me unless I am isolated from others, and the events of our world, but as I said just being able to sleep again and this has been a godsend.

continued...

... Previously, even in my safe places, I couldn't do that. So for me the value of the AS unit is that once again I can wake rested after so, so many years. All the drugs I have taken over the years never did this! Also, I notice that the AS helps with the pain and discomfort from my wounds. A little relief from this discomfort helps as well, especially with my kidney problems today as a result of all the years of having to take the pain killers, NSAIDS and anti-inflammatories. I may not have had the kidney problems I do today if I had the availability of an Alpha-Stim. Therefore, I wish the VA and the military would look at this type of therapy versus prescribing drug after drug to our veterans. I can't help but feel that a sizable amount of the veterans problems are causally related to the free-welling nature of the doctors and the systems prescribing drugs so easily. We are awash in this mentality and it has not solved the problems for our veterans. Why doesn't the VA and the military evaluate the benefits of treatments of things like the Alpha-Stim? It makes you wonder.”

UTILIZATION OF CES IN THE WARTIME THEATER



- n 9 Alpha-Stim 100 devices were donated to the 55th MED CO (CSC) for Prevention and Restoration Teams at 8 separate locations throughout Central Iraq, to include 1 device for the Behavioral Science Consultant, 44th MEDCOM, and IAW with Army Regulations (approval received at highest levels of MNC-I Command)**
- n Most officers in charge of their respective teams failed to train themselves and their team members to effectively utilize CES**
- n In Ar Ramadi, the seat of the insurgency, CES treatment was offered and requested on a daily basis, often well into the night due to mission demands of both the 3rd Brigade Combat Team and the 2nd Marine Division/Marine Expeditionary Force**

MINES IN THE WORLD'S MOST DANGEROUS CITY.....

AR RAMADI AL ANBAR PROVINCE









The New Combat Stress Control Armamentarium

- n Among throngs of Soldiers and members of the 2nd Marine Division's 2nd Marine Expeditionary Force , 2nd Anglico, and the Explosive Ordnance Detail, the Department of Defense Fire Department, and members of the Pennsylvania National Guard's Bloody Buckets, there was no shortage of incoming Service Members and Marines seeking services**
- n In desperation for brief moments of reprieve from relentless anxiety, panic, sleeplessness, and depths of depression that penetrated their every waking moment, the only route to relief was provided by nightly (or whenever missions permitted) CES and MET treatment sessions**
- n Whether chronic and intractable or acute pain from combat-related injuries or that which stemmed from the psychological impact of war, there was no short order of either**
- n The very fact that the combat stress folks had "gadgets" on board, facilitated the arrival of numerous new recruits for mental health and pain management interventions**

- n Though means and time for documentation of treatment effects and outcomes were scarce (or insufficient supplies of paper records or charts were unavailable), results were overwhelmingly and even exceedingly positive in every case, without exception**
- n Behavioral science specialists rapidly became adept at utilizing CES and MET for multiple conditions in conjunction with other therapeutic interventions, as well as treatment of acute and chronic pain.**
- n Of many cases of those Soldiers, Marines and Air Force personnel referred to Charlie Med, our level IV trauma center at Ar Ramadi, for anti-depressant, anti-anxiety, and sedative-hypnotic (sleep) medication evaluation, prescription, and monitoring, none demonstrated the degree of improvement in decreased symptomatology as those treated with CES and MET**
- n Psychopharmacological interventions routinely offered minimal benefits with intolerable side effects, requiring prescription of a diverse number of medications over time in attempts to find sufficiently efficient cocktails**
- n Additionally, specific anti-depressants were typically unavailable in the wartime theater, as delivery to the outermost reaches of wartime theater was poor or impossible at best**



The Downside of SSRI's in the Theater of Operations

- n Frequently, medications resulted in significant functional impairments, incompatible with mission performance**
- n These side effects unquestionably endangered those for whom they were prescribed, as well as the remainder of those Soldiers and Marines whose lives depended upon alert and mentally-focused comrades in arms**
- n Additionally, cumulative impact of conditions involving temperatures exceeding 125 degrees Fahrenheit, combined effects of relentless heat and the wearing as much as 100 pounds body armor, Kevlar, countless rounds of ammunition and essential gear; and lastly, endless days of sleep deprivation, could readily potentiate more untoward effects of (some of) these classes of medications**

- n In essence and oftentimes, risks of ingesting these medications in the combat zone readily outweighed the benefits**
- n When shelves of Battalion Aid Stations ran dry of supplies, psychotropic medications were frequently first to be depleted**
- n This placed unlucky recipients of these prescriptions at increasing risk for onset of Serotonin Discontinuation Syndrome (severe flu-like symptoms, including headache, diarrhea, nausea, vomiting, chills, dizziness, fatigue, insomnia, psychomotor agitation, impaired concentration, vivid dreams, depersonalization, irritability and possible suicidal thoughts). Symptoms may last from one to seven weeks, in varying intensity**

Black Box Warnings

- n In July of 2007, the FDA released yet another set of black box warnings to the public for “Suicidality in Young Adults Taking Antidepressants”
- n The FDA has proposed that product labeling include the following information:
 - “Patients 18 to 24 years old who are on these drugs may be at increased risk for suicidal thinking and suicide attempts”.
 - “This new warning would be added to the black box section of the product label, which already warns about this risk in children and adolescents”.

n The following medications have been listed by the FDA as causing increased risk of suicidality in 18 to 24 year old adults:

Anafranil (clomipramine)
Asendin (amoxapine)
Aventyl (nortriptyline)
Celexa (citalopram hydrobromide)
Cymbalta (duloxetine)
Desyrel (trazodone HCl)
Elavil (amitriptyline)
Effexor (venlafaxine HCl)
Emsam (selegiline)
Etrafon (perphenazine/amitriptyline)
Fluvoxamine maleate
Lexapro (escitalopram oxalate)
Limbital (chlordiazepoxide/amitriptyline)
Ludiomil (maprotiline)
Marplan (isocarboxazid)
Nardil (phenelzine sulfate)
Nefazodone HCl

and more...

- Norpramin (desipramine HCl)
- Pamelor (nortriptyline)
- Parnate (tranylcypromine sulfate)
- Paxil (paroxetine HCl)
- Pexeva (paroxetine mesylate)
- Prozac (fluoxetine HCl)
- Remeron (mirtazapine)
- Sarafem (fluoxetine HCl)
- Seroquel (quetiapine)
- Sinequan (doxepin)
- Surmontil (trimipramine)
- Symbyax (olanzapine/fluoxetine)
- Tofranil (imipramine)
- Tofranil-PM (imipramine pamoate)
- Triavil (perphenazine/amitriptyline)
- Vivactil (protriptyline)
- Wellbutrin (bupropion HCl)
- Zoloft (sertraline HCl)
- Zyban (bupropion HCl)

- n As the average age of members of the Armed Forces in the Wartime Theater of Operations is well within the range for which the FDA has issued a new warning, there is every excellent reason NOT to prescribe SSRI's for the populations of military Service Members on active duty, let alone anyone else under the age of 24
- n In the UK, SSRI's were banned for under-18 year olds except for Prozac (which is the weakest of the SSRI's), yet nothing miraculous happens to our physiology on our 18th birthday

- n Stated simply, there are no black box warnings for CES or MET and contraindications are negligible or nonexistent
- n The principal problem encountered in the War-time Theater was having an inadequate supply of silver electrodes (only one set at our disposal and no running water in which to wash them)
- n We resolved this with the use of isopropyl alcohol pads to sanitize electrodes for regular reuse

- n Otherwise, the effects of CES are cumulative, as borne out by more than 25 years of clinical research
- n As the Soldiers (and civilians) see improvements in their functioning, mood states, and pain levels, compliance improves



CES VERSUS EVERYTHING ELSE



WHEN TO IMPLEMENT CES

n Contraindications

1. Pregnancy (due to liability concerns only)
2. Implanted cardiac devices (pacemakers)

n Appropriate in clinical settings for treatment of:

Depressive disorders

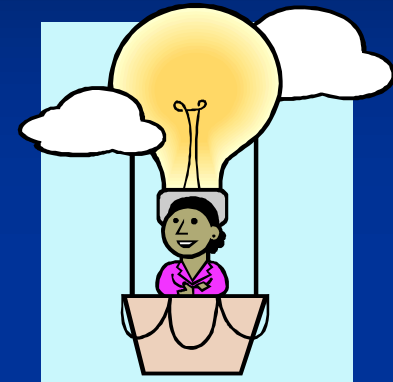
Anxiety disorders

Sleep disorders

Acute and chronic intractable pain

Headaches (migraine, vascular, tension,
and cluster)

n Adjunctively (complementary) with many other types of psychotherapeutic interventions



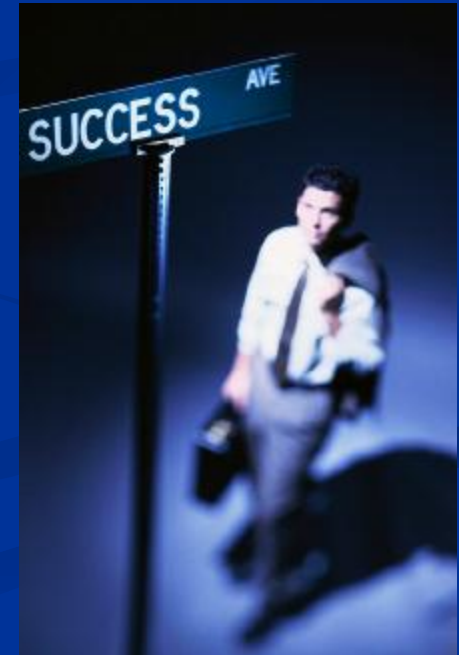
TREATMENT FAILURES WITH CES

- n 20 patients utilizing CES
 - 1 patient reported increased insomnia on 1 occasion
- n 1 patient reported no change in headache pain intensity



TREATMENT SUCCESSES

- n 50% OF PATIENTS SUFFERING FROM CHRONIC PAIN EXPERIENCED SIGNIFICANT IMPROVEMENTS IN REDUCTION OF PAIN INTENSITY



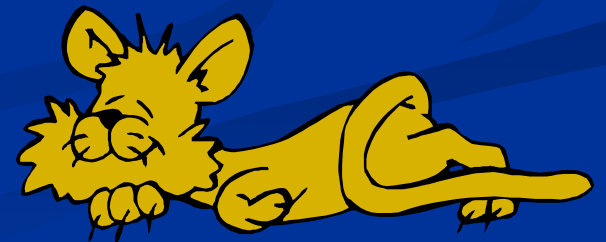
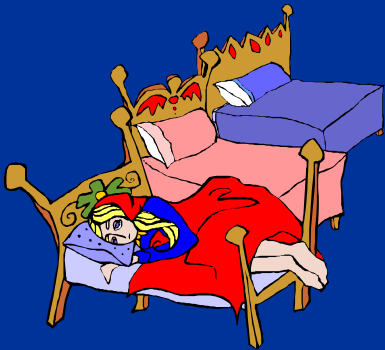
n 100% OF PATIENTS DIAGNOSED WITH ANXIETY DISORDERS EXPERIENCED SIGNIFICANTLY DIMINISHED SYMPTOMS WITH CES



n 79% OF PATIENTS WITH DEPRESSIVE DISORDERS REPORTED A SIGNIFICANT DECLINE IN SYMPTOMS



n 77% OF PATIENTS SUFFERING FROM SLEEP DISORDERS REPORTED EITHER IMPROVEMENTS OR COMPLETE RESOLUTION OF THEIR INSOMNIA



IN SUMMARY

The worst nightmare for our Armed Forces and likely for all of America, has become the widespread reliance upon the magic bullet and quick fix mentality of pill prescriptions and the encouragement of looking for answers in bottles of SSRIs, anxiolytics, and sedative-hypnotics for sleep production.



n Oftentimes, tolerance to meds occurs in rapid succession, demanding prescriptions of larger and more frequent doses in a gradual progression in the quest for obscure relief. When the maximum therapeutic dosage is reached for each of any numbers of these medications and the end of the line reached, there is nothing left but desperation and usually, little or no improvement in one's psychological condition.

- n With CES and MET, there are benefits without side effects.
- n Ethically speaking, it is ours, as health care providers, to provide all things therapeutic for our veterans and the thousands of military souls suffering from wounds that do not bleed.
- n It is the moral obligation of health care providers to possess adequate knowledge and skill to provide those interventions for which they are technically and clinically trained for the good of the patient, the Soldier, the Marine, the Service Member, and our patients in the civilian sector as well.

The New Standard

- n The exceptionally distressing and shameful fact is that we are simply not making use of the most effective and powerful weaponry in our stockpile of treatment options in order to ameliorate the psychological impact and human toll of the battlefield.
- n CES may therefore unquestionably be the unequivocal platinum standard of treatment, regardless of the setting or the uniform.



QUESTIONS?

