Military Service Member and Veteran Self Reports of Efficacy of Cranial Electrotherapy Stimulation for Anxiety, Posttraumatic Stress Disorder, Insomnia, and Depression

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Abstract

Cranial electrotherapy stimulation (CES) is being prescribed for service members and veterans for the treatment of anxiety, posttraumatic stress disorder (PTSD), insomnia and depression. The purpose of this study was to examine service members' and veterans' perceptions of the effectiveness and safety of CES treatment. Service members and veterans (N=1,514) who had obtained a CES device through the Department of Defense or Veterans Affairs Medical Center from 2006-2011 were invited to participate in the web based survey via email. One hundred fifty-two participants returned questionnaires. Data were analyzed using descriptive statistics. Participants reported clinical improvement of 25% or more from using CES for anxiety (66.7%), PTSD (62.5%), insomnia (65.3%) and depression (53.9%). The majority of these participants reported clinical improvement of 50% or more. Respondents also perceived CES to be safe (99.0%). Those individuals who were not taking any prescription medication rated CES more effective than the combined CES and prescription medication group. CES provides service members and veterans with a safe, noninvasive, nondrug, easy to use treatment for anxiety, PTSD, insomnia, and depression that can be used in the clinical setting or self-directed at home.

Cranial electrotherapy stimulation (CES) is a noninvasive, prescriptive medical treatment approved by the Food and Drug Administration for anxiety, insomnia, and depression. About the size of a smart phone, a CES device uses electrodes typically placed on both ear lobes to send a low level (less than 1 mA), pulsed electrical current transcranially through the brain.[1] An EEG analysis of 30 subjects who received one 20 minute CES treatment showed significant increases in alpha activity (increased relaxation) and decreases in delta activity (increased alertness) and theta activity (increased ability to focus attention).[2] These changes induce a calm, relaxed, yet alert state. A recent functional magnetic resonance imaging (fMRI) study provides irrefutable proof that CES causes cortical brain deactivation in the midline frontal and parietal regions of the brain after one 20 minute treatment.[3] Many psychiatric and sleep problems are thought to be caused by cortical activation from anxiety or attention disorders.[4,5] Thus, the fMRI study provides additional insight into the mechanism for the effectiveness of CES.

Since the early 2000s, Department of Defense (DoD) and Department of Veterans Affairs (VA) practitioners have prescribed CES for the treatment of anxiety, Posttraumatic stress disorder (PTSD), insomnia, depression, pain, and headaches.[6,7] CES is classed as a tier II modality for pain by The Army Surgeon General's Pain Management Task Force.[8] When CES is used primarily for centralized pain, it also can decrease anxiety, insomnia, and depression, common comorbidities of pain. Tan and colleagues[9] compared service members' and veterans' preferences for 5 different therapeutic modalities for decreasing stress, anxiety, insomnia, and pain at a veterans' outpatient pain management clinic. Participants could choose which device they wanted to use and could use a different device if they chose at future clinic visits. Cranial electrotherapy stimulation was selected 73% of the time (n=144), while the other 4 stress reducing modalities were selected from 4% to 11% of the time (n=53).

The purpose of this nonprobability, purposive sampling survey was to examine service members' and veterans' perceptions of the effectiveness and safety of CES for the treatment of anxiety, PTSD, insomnia, and depression. It was part of a postmarketing surveillance report for the Food and Drug Administration.

Safety

Cranial electrotherapy stimulation has an excellent safety profile. Electromedical Products International, Inc (EPI) (Mineral Wells, TX) reported, based on a survey

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Table 1. Alpha-Stim CES studies on anxiety.

Principal Investigator	Total (n)	Subjects	Study Type	Findings
H. J. Kim (2008)[11]	60	Preoperative patients	RCT, IB	CES group had significantly lower scores from baseline on the Likert Anxiety Scale than control group at end of study ($P<.01$, $d=-0.88$).
R. C. Cork (2004)[12]	74	Fibromyalgia patients	RCT, DB, OL	CES group had significantly lower scores from baseline on the Profile of Mood States Scale (POMS), indicating less anxiety, than sham group at end of study ($P<.01$). Open label CES group had significantly lower scores on POMS at posttest from baseline scores ($P<.001$).
A. S. Lichtbroun (2001)[13]	60	Fibromyalgia patients	RCT, DB, OL	CES group had significantly lower scores on the Profile of Mood States Anxiety Subscale (POMS-A), indicating less anxiety, from baseline than sham group at end of study ($P=.02$, $d=-0.60$). There was no significant difference in Open Label crossover group from pretest to posttest on POMS-A ($P>.05$).
R. L. Winick (1999)[14]	33	Dental patients	RCT, DB	CES group had significantly lower scores from baseline, indicating less anxiety, on the Visual Analog Scale ($P<.01$, $d=-0.61$) and higher scores on Likert Anxiety Scale, indicating less anxiety ($P<.01$) than sham group at end of study.
A. Bystritsky (2008)[15]	12	General anxiety disorder patients	OL	Anxiety scores decreased significantly on the Hamilton Anxiety Rating Scale from baseline to end of study ($P=.01$, $d=-1.52$). Anxiety scores were significantly lower on the Four-Dimensional Anxiety and Depression Scale at end of study from baseline ($P<.01$, $d=-0.75$).
S. J. Overcash (1999)[16]	197	Anxiety disorder patients	OL	Subjects rating of anxiety was significantly less on Numerical Anxiety Rating Scale, 0-100, from baseline to posttest ($P<.05$).Subjects' physiological measures of anxiety–EMG, EDR and Temp–changed significantly from baseline to posttest indicating less anxiety ($P<.05$).

RCT indicates randomized control trial; IB, investigator blind; DB, double blind; and OL, open label clinical study.

Table 2. Alpha-Stim CES studies on insomnia and depression.

Principal Investigator	Total (n)	Subjects	Study Type	Findings
Insomnia CES Studies				
A. G. Taylor (2013)[17]	46	Fibromyalgia patients	RCT, DB	CES group had significantly lower scores on General Sleep Disturbance Scale (indicating less sleep disturbance) than sham from baseline at end of study ($P<.001$, $d=-0.30$) and completed the study with scores below the range of insomnia.
A. S. Lichtbroun (2001)[13]	60	Fibromyalgia patients	RCT, DB, OL	CES group had significantly higher scores on Numerical Sleep Quality Rating Scale, 0-10, than sham group at end of study ($P<.02$, $d=-0.54$).
Depression CES Studies				
R. R. Mellon (2009)[18]	21	Jail security and patrol officers	RCT, DB	CES group had significantly less depression from baseline than sham group at end of study on Beck Depression Inventory ($P<.01$) and on Brief Symptom Inventory Depression scale ($P<.05$).
A. Bystritsky (2008)[15]	12	General anxiety disorder patients	OL	Depression scores were significantly less on Hamilton Depression Rating Scale at end of study from baseline ($P=.01$, $d=-0.41$).

RCT indicates randomized control trial; IB, investigator blind; DB, double blind; and OL, open label clinical study.

of Alpha-Stim CES users, that during 2007-2011 there was a total of 8,248,920 Alpha-Stim CES treatments (1,982,520 individual users treatments plus 6,266,400 in-office treatments by practitioners). Any side effects that occurred were mild and self-limiting. Reported side effects from all sources (EPI survey and the scientific literature) are 1% or less. These include dizziness, skin irritation at electrode sites, and headaches. Headaches and dizziness are usually associated with a current setting too high for the individual. The symptoms normally resolve when the current is decreased. Irritation at the electrode site can be decreased by using alternate sites for placement of electrodes. There have been no serious adverse effects reported from using CES during 31 years on the market in the United States.[10]

Efficacy

The first scientific investigations of the effect of CES were performed by Russian scientists in the 1950s and 1960s. These studies focused on the effect of CES on inducing sleep. After the 1966 International Symposia for Electrotherapeutic Sleep and Electroanesthesia in Graz, Austria, American scientists began investigating the effectiveness of CES for treating anxiety, insomnia, depression, and substance abuse. Numerous publications on these topics appeared during the 1970s. These early studies were typically small and had methodological limitations reflecting the research designs used in the time period during which they were conducted. However, the findings from the studies were consistently positive, showing CES decreased anxiety, insomnia, and depression.[1]

Over the past 15 years or so, the sophistication of the research designs and the quality of CES research improved substantially. Four randomized clinical trials (RCTs) investigated the efficacy of CES in treating state anxiety (Table 1).

Three of the RCTs, used a double-blind sham controlled design, while one RCT used an investigator-blind design. In these RCTs, the active CES group had significantly lower scores on state anxiety outcome measures than the sham or control group. Three RCTS on anxiety included Cohen's *d* effect sizes that ranged from *d*=-0.60 (moderate) to *d*=-0.88 (high). Two open clinical studies found a significant difference from baseline to the endpoint of the study, with subjects having lower state anxiety scores at the endpoint of the study. Bystritsky and colleagues reported Cohen's *d* effects sizes for 2 anxiety outcome measures: *d*=-1.53 on the Hamilton Anxiety Rating Scale (very high) and *d*=-0.75 (moderate) on the Four-Dimensional Anxiety and Depression Rating Scale. Cranial electrotherapy stimulation was also shown to significantly decrease insomnia and depression (Table 2). All studies that investigated the effect of CES used reliable and valid scales for the measurement of outcomes.

Methods

The CES Device

The Alpha-Stim CES device with ear clips electrodes (0.5 Hz, 100–600 μA, 50% duty cycle, biphasic asymmetrical rectangular waves) was used in this study. Two electrodes that clip onto the ear lobes are used to send a mild electrical current through the brain. Treatment duration is a minimum of 20 minutes, but may be an hour at least one time daily. PTSD patients sometimes do a one hour CES treatment several times a day. During acute PTSD episodes, patients may use CES for extended periods of time (several hours) until symptoms decrease. While CES treatments should last a minimum of 20 minutes to achieve the desired effect, extended use of CES has no adverse side effects and is well tolerated.

The Questionnaire

One thousand five hundred fourteen (N=1,514) active duty service members and veterans who obtained an Alpha-Stim CES device through the DoD or VA medical centers from 2006 to 2011 were invited to participate in the web-based survey via email. Email addresses were obtained from prescription information for CES devices that was on file at EPI, the manufacturer of the device. All of the potential participants had been taught, using a standardized DoD or VA CES protocol, how to use self-directed CES at home. Participants either voluntarily chose to respond or not to respond to the questionnaire. Survey Monkey is the professional website (http://www.surveymonkey.com) for survey research that was used for this study. Respondents completed the questionnaire on-line from September 1, 2011, to October 1, 2011. Of the 1,514 persons who were invited to participate in the survey, 152 (N) responses to the questionnaire were received, yielding a response rate of 10%. Although response rates vary by the population sampled, a response rate somewhere between 15% and 40% is common for web-based surveys.[19,20]

The questionnaire contained 27 questions that covered demographic information, prescription medication use, and current exercise activity, as well as questions asking respondents to rate the effectiveness of CES technology for treating anxiety, PTSD, insomnia, and depression. A single item, 7-point Likert scale, which has established validity in the literature,[21] was used to measure respondents' perceived effectiveness of CES for anxiety, PTSD, insomnia, and depression. A sample question follows:

> If you are using CES for your PTSD, since starting CES, rate your improvement as:
>
> a. Worse (negative change)
>
> b. No change (0%)
>
> c. Slight improvement (1% to 24%)
>
> d. Fair improvement (25% to 49%)
>
> e. Moderate improvement (50% to 74%)
>
> f. Marked improvement (75% to 99%)
>
> g. Complete recovery (100%)

Results

Data were analyzed using descriptive statistics. The characteristics of respondents, their use of CES technology, conditions for which they used CES, how often they used CES, and the length of time they had used CES are shown in Table 3. In addition to analysis of improvement-related questions on anxiety, PTSD, insomnia, and depression, questions were also interpreted in consideration of respondents' use of prescription medication while using CES. There were 152 responses to the questionnaire. Seven questionnaires did not include any effectiveness and safety data. Thus, the valid sample size was N=145 for the analysis of these questions.

Safety and Overall Perceived Efficacy

Of the 145 persons responding to "Do you consider CES safe and effective?", 99% reported that they view CES as safe and effective. Of the 1% of respondents (n=2) reporting CES as unsafe or ineffective, the reasons given were (1) that they were never shown how to use CES properly, and (2) CES was ineffective for their medical condition.

Table 3. Respondent characteristics and use of CES.

Characteristics	n (%N)	Characteristics	n (%N)
Military status (N=152)		Conditions for which respondents used CES technology* (N=145)	
Active duty service members	109 (72%)	Anxiety	114 (78%)
Veterans	43 (28%)	Depression	89 (61%)
Age (N=152)		Insomnia	98 (67%)
Range: 19 to 67 years (mean=38, SD=10)		PTSD	88 (60%)
Gender (N=152)		How often respondents used CES (N=145)	
Male	114 (75%)	Once a day	72 (50%)
Female	33 (22%)	Twice a day	35 (24%)
No response	5 (3%)	2 to 3 times a day	6 (4%)
Currently using CES? (N=152)		3 or more times a day	4 (3%)
Yes	125 (82%)	No response	28 (19%)
No	23 (15%)	Length of time using CES (N=145)	
No response	4 (2%)	90 days	19 (13%)
Currently taking at least one prescription drug? (N=152)		4 months	9 (6%)
Yes	112 (73%)	5 months	5 (3%)
No	40 (27%)	6 months	17 (12%)
Currently exercise regularly? (N=152)		9 months	5 (3%)
		1 year	31 (21%)
Yes	116 (76%)	2 years	20 (14%)
No	31 (20%)	3 years	7 (5%)
No response	5 (3%)	No response	32 (22%)

*Use of CES for the following conditions was reported as 4% or less: attention deficit disorder, spasticity, antibiotic, anti-inflammatory, acid reflux, narcolepsy, Parkinson' disease, erectile dysfunction.

Anxiety

Thirty-one subjects (21.3%) reported that they were not currently using CES for anxiety. One hundred fourteen subjects (combined sample taking and not taking prescription medications regularly) using CES for anxiety responded to, "If you are using CES for anxiety, since starting CES, rate your improvement as …." Figure 1 shows the results for the total group (N=114), the CES only no medication group (n=26), and the CES and medication group (n=88).

Posttraumatic Stress Disorder

Fifty-six of the subjects (38.6%) reported not using CES for PTSD. Although PTSD is an anxiety disorder, it was included as a separate variable because of its importance in the treatment of service members and veterans.[22] Eighty-eight subjects (combined sample taking and not taking prescription medication regularly) using CES for PTSD responded to "If you are using CES for PTSD, since starting CES, rate your improvement as...." The findings of the total group (N=88), CES only no medication group (n=18), and CES and medication group (n=70) are shown in Figure 2.

Insomnia

Forty-six subjects (31.7%) reported that they did not use CES for insomnia. Ninety-eight subjects (combined sample taking and not taking prescription medication regularly) who used CES for insomnia responded to , "If you are using CES for insomnia, since starting CES, rate your improvement as…." The findings of the total group (N=98), CES only no medication group (n=21), and CES medication group (n=77) are shown in Figure 3.

Depression

Fifty-six subjects (38.6%) reported that they were not using CES for depression. Eighty-nine subjects (subjects combined sample taking and not taking prescription medication regularly) using CES for depression responded to "If you are using CES for depression, since starting CES, rate your improvement as…." The findings of the total group (N=89), CES only no medication group (n=13), and CES medication group (n=76) are shown in Figure 4.

Determining Important Clinical Improvement

Dworkin and colleagues[23] defined the criteria for important clinical improvement as follows:

> Improvement of moderate clinical importance is 30% to 49%, and improvement of substantial clinical importance, the highest category, is 50% or more.

While the criteria were developed to evaluate clinical trial outcomes on chronic pain, it provides a useful framework for the assessment of clinical improvement in anxiety, PTSD, insomnia, and depression as well. For this study, improvement of moderate clinical importance was defined as 25% to 49% because the Likert scale which has been validated for use in measuring CES outcomes used 25% increments for categories. Using a conservative approach, the "Slight Improvement" (1% to 24%) category on the 2011 Alpha-Stim CES service members and Veterans survey was excluded, leaving the top 4 categories of "Fair Improvement" (25% to 49%), "Moderate Improvement" (50% to 74%), "Marked Improvement" (75% to 99%) and "Complete Improvement" (100%). Participants reported clinical improvement of 25% or more from using CES for anxiety (66.7%), PTSD (62.5%), insomnia (65.3%), and depression (53.9%). The majority of service members and veterans who reported improvement of 25% or more had improvement in

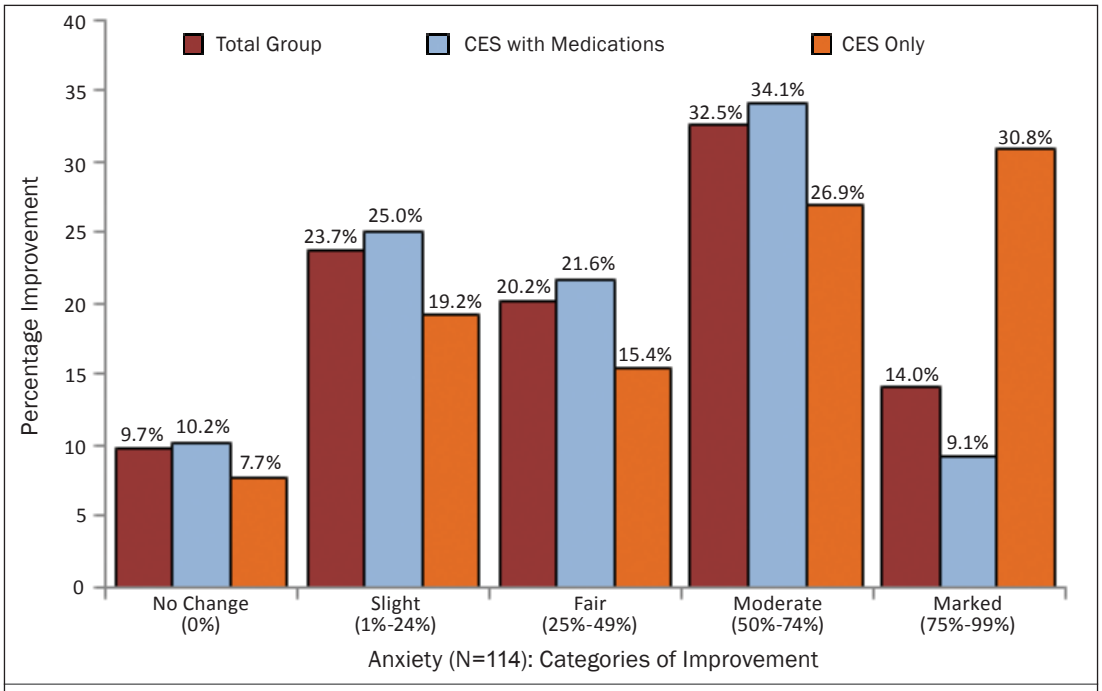

Figure 1. Perceived Improvement in anxiety with use of CES by group.

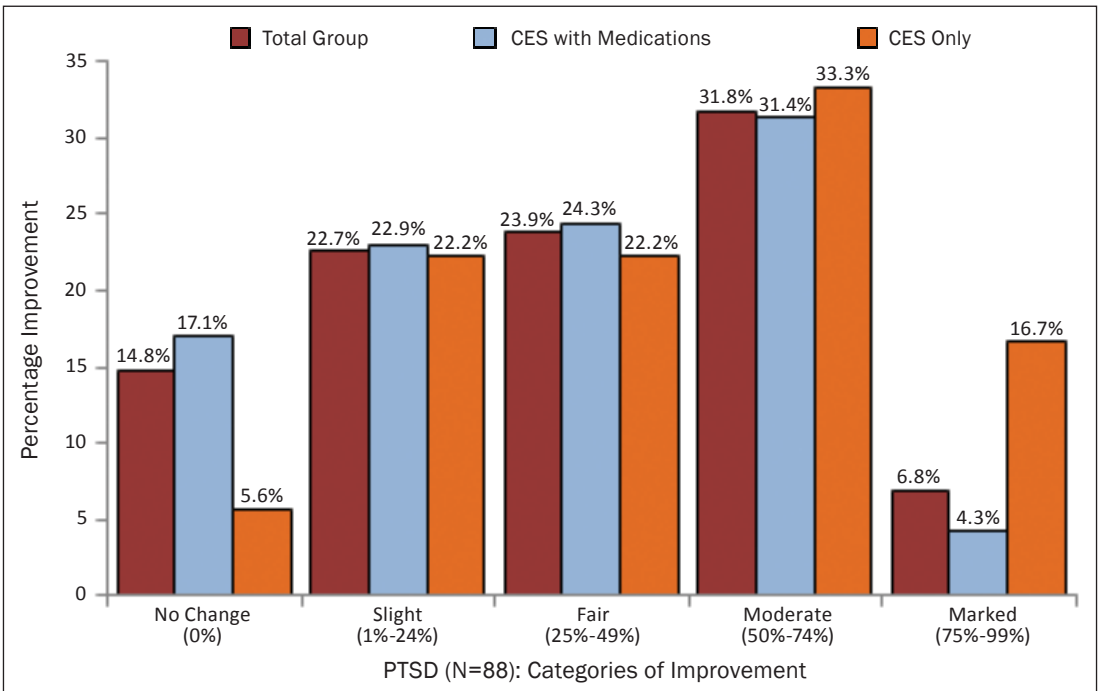

Figure 2. Perceived Improvement in PTSD with use of CES by group.

the highest category, "substantial clinical importance," (50% or more) on all variables: anxiety, PTSD, insomnia, and depression, as shown in Figure 5.

Prescription Medication Use

Of the 112 respondents who reported they took at least one prescription medication, 98 provided the name of the drug or condition for which it was taken. The number of prescription medications taken ranged from one to 11, with a mean of 2.6 and a median of 2.0. The types of medications taken are shown in Table 4. Medications that are used clinically for anxiety and depression were placed in the anxiety category.[24] Medications used primarily for depression were placed in the depression

category. Only those medications categorized as sedative hypnotics were placed in the insomnia category. Only those drugs specifically approved for migraine headaches were included in the migraine headache category, while all narcotic and other pain medications were included in the pain category, the subject of a separate paper.

Table 4. Prescription Medications Use by Condition.

Anxiety	45.9%
Depression	44.8%
Pain	38.7%
Insomnia	27.5%
Hypertension	16.3%
Seizure Control	11.2%
Migraine Headache	9.0%
Schizophrenia/Bipolar	9.0%

Comparison of CES with Drug Therapy

Several of the most common drugs used to treat anxiety, PTSD, insomnia, depression, pain and headaches were compared to the findings of the Alpha-Stim service member and civilian surveys as shown in Figure 6. CES data from October 2011 Military Service Member and Veterans study (N=152) and the CES Civilian User Survey (N=1,745) August 2011 were used. Pharmaceutical Survey Data were obtained from on-line WebMD user surveys (http://www.WebMD.com/drugs).

The Alpha-Stim CES civilian survey was conducted in August 2011 from data collected between July 2006 and July 2011 (http://www.alpha-stim.com). The final sample size from the civilian survey was 1,745 responders from a mail survey of 4,590 (38% useable responses). The WebMD drug survey asked civilians the question: "This medication has worked for me?" Respondents could choose to answer in one of 5 categories, with "1" being the lowest to "5" being the most effective. The sample size for the drugs selected ranged from N=62 to N=2,238. The CES survey questionnaire asked respondents to rate their improvement for a specific condition based on using CES. Subjects could choose one of 7 categories: worse (negative change), no improvement (0%), slight improvement (1% to 24%), fair improvement (25% to 49%), moderate improvement (50% to 74%), marked improvement (75% to 99%), and complete recovery (100%). While the questions in the WebMD and CES surveys were slightly different, all surveys asked questions about effectiveness. The WebMD data were changed to percentages and ranged from 1% to 100%. Two categories were excluded from the CES survey as they were not included in the WebMD survey: worse (negative change) and no change (0%). The categories of "worse (negative change)" or "no change" reflected less than 1% of the responses in all instances (ie, on all questions). The upper 5 categories which ranged from 1% to 100% were used for comparison. The scale was the same, 1% to 100% for the data from all surveys. The comparison of the data from the 2 surveys is both appropriate and justifiable based on the item content (ie, content/construct validity) and the format of item response.[19]

Comment

It is not surprising that the response rate to the survey was not higher. The majority of persons asked to participate in the survey were active duty service members.

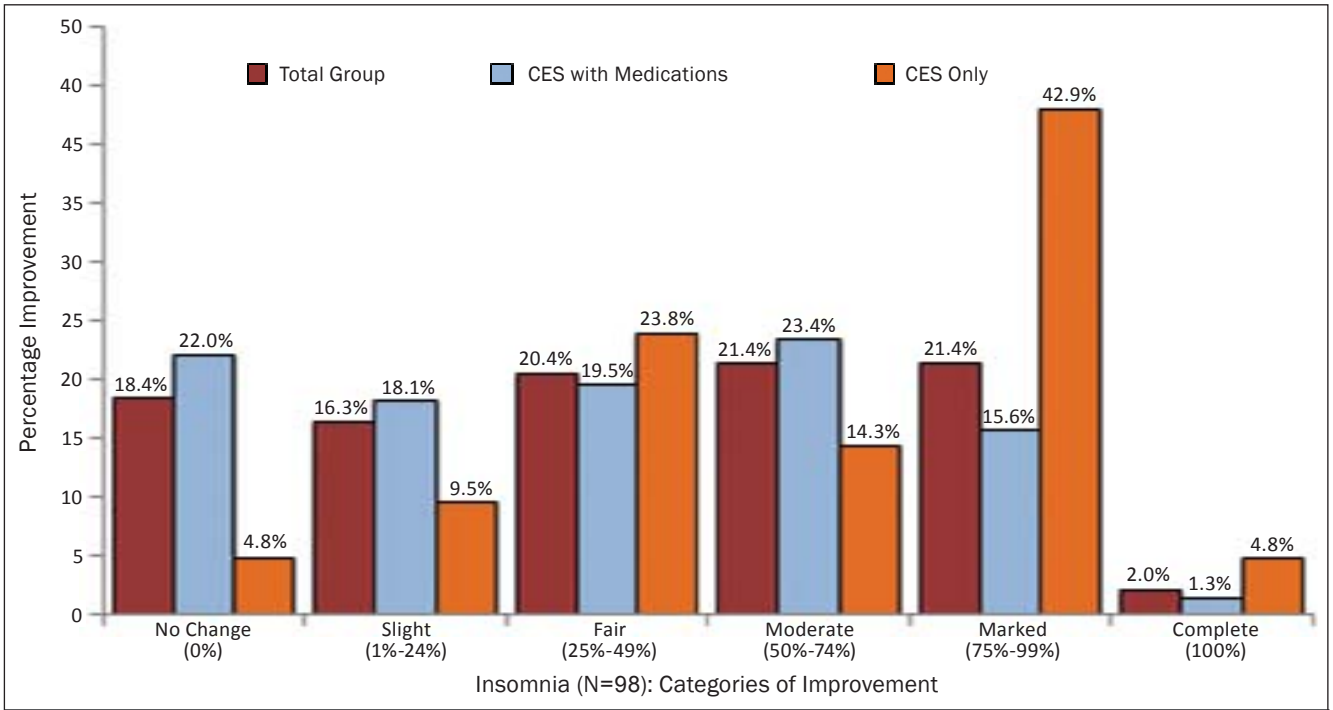

Figure 3. Perceived Improvement in insomnia with use of CES by group.

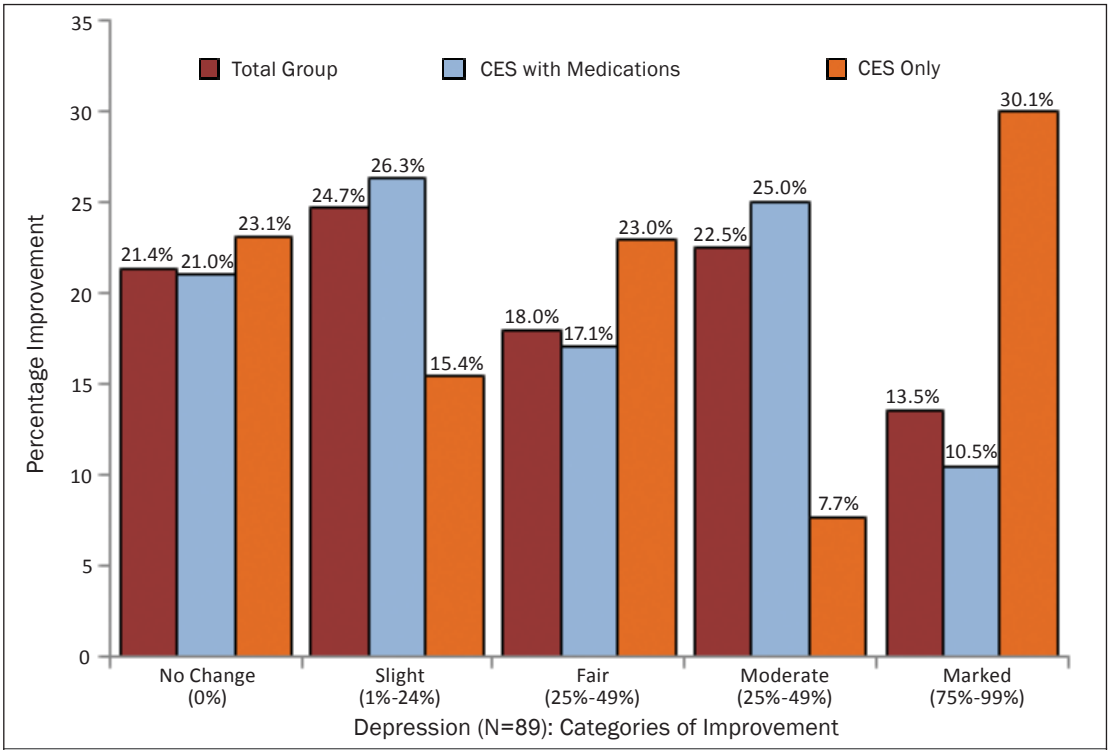

Figure 4. Perceived Improvement in depression with use of CES by group.

Many email addresses may not have been valid because the survey covered a 6-year period and some may have moved, were discharged, or may have elected not to respond to the email if they were no longer using CES. This study supports the efficacy and safety of CES technology for the treatment of anxiety, PTSD, insomnia, and depression in service members and veterans. The findings are consistent with findings of previous research studies on CES. The effectiveness of CES in a military population was comparable to the effectiveness of drugs commonly used in the treatment of the same conditions in the civilian population.

Ninety-nine percent of subjects in this survey considered CES technology to be safe. An important safety benefit of CES is that it leaves the user alert and relaxed after treatment, in contrast to drugs that can have adverse side effects and affect service members' ability to function on missions that require intense focus and attention.[25] This is particularly true in the combat theater of operations.

The information on prescription medication use provides a general view of drugs used by respondents for their specific condition(s). The findings that a high percentage of respondents took prescription medications for anxiety (45.9%), depression

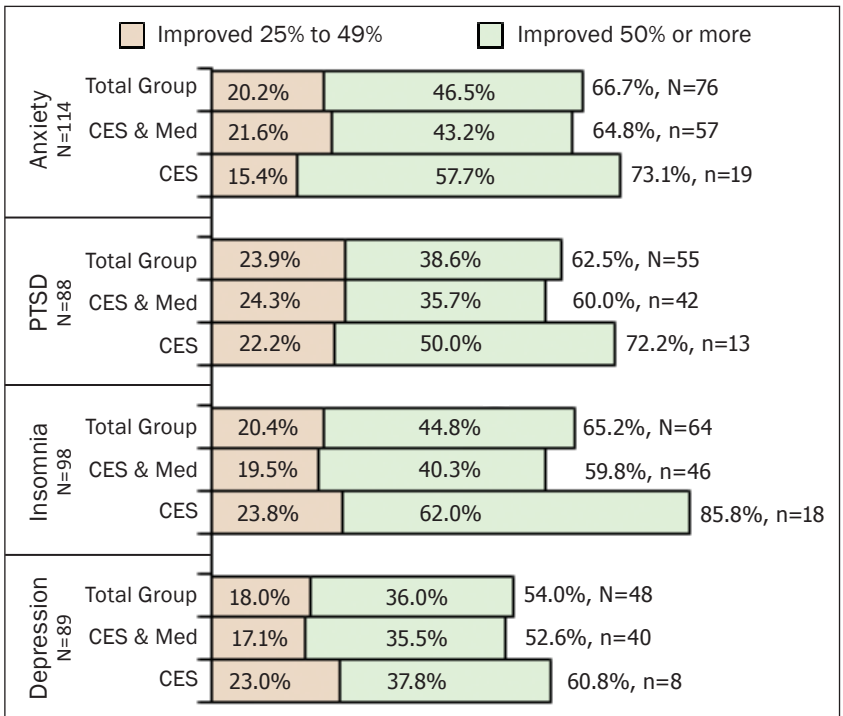

Figure 5. Service members and veterans who had improvment of moderate (25% to 49%) and substantial (50% or more) clinical importance.
Note: CES & Med indicates CES and medication. CES indicates CES alone.

(44.8%), pain (38.7%), and insomnia (27.5%) is consistent with the literature.[6,7] The importance of controlling for medication type and dosage in future CES studies is a valuable outcome of this survey. It would also be helpful to classify the severity of illness of the subjects in future studies. While it appears that medication may influence the effectiveness of CES technology, it is possible that respondents taking prescription medication had far more serious symptoms and medical and psychological conditions than the no medication group. The group sizes were unequal. The "CES only, no medication" group was considerably smaller, ranging from 13 to 26 subjects, in comparison to the CES medication groups that ranged from 53 to 88 subjects. This may account for the differences in scores between the groups. However, the effect of medication appears to be an important confounding variable when investigating the efficacy of CES.

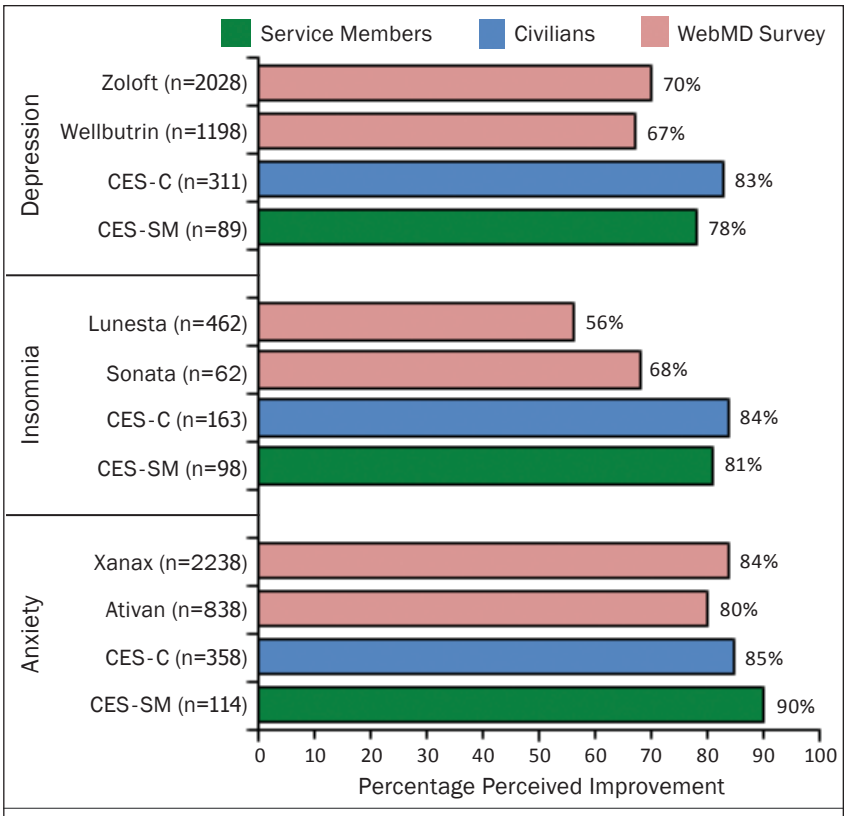

Figure 6. Comparison of service members' (SM) and civilians' (C) perceived responses to Alpha-Stim CES and drug therapy. CES data from Alpha-Stim Military Service Member Survey (N=152) and Alpha-Stim Patient Survey (N=1,745), October 2011. Pharmaceutical survey data from WebMD (http://www.WebMD.com/) accessed October 28, 2011.

Conclusions

The results of this survey are compelling and provide the foundation for a rigorous placebo controlled RCT that investigates the effectiveness of CES for treating anxiety, PTSD, insomnia, and depression in service members and veterans. In addition, this study also examines the influence of medication on CES efficacy outcomes. This study provides evidence that service members and veterans perceived CES as an effective treatment for anxiety, PTSD, insomnia, and depression. CES can be used either as an adjunct to pharmaceutical therapy or as a standalone therapy, providing service members and veterans with a safe, noninvasive, nonpharmacologic treatment for anxiety, PTSD, insomnia, and depression that can be used in the clinic setting, including the wartime theater clinics, or self-directed at home.

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