Cranial Electrotherapy Stimulation: For Anxiety, Insomnia, Depression, PTSD, COS, and Pain

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¬ Fellow, American Institute of Stress
¬ Editor, Journal of Neurotherapy and Practical Pain Management
¬ Member, Inter-Pain (Germany/Switzerland)
¬ Pain, Stress and PTSD Consultant to US Army and VAMC

COL Kathy Platoni, PsyD
¬ Former Deputy Commander for Clinical Services; Officer in Charge of Team Ar Ramadi, Al Anbar Province, Operation Iraqi Freedom
¬ Chief of Mental Health, 307th Medical Group US Army Reserves

© 2007 Dr. Daniel L. Kirsch, EPI, Mineral Wells, TX and COL Kathy Platoni, USAR Centerville, OH
Perspective:

The average pain reduction from the long-term use of analgesics is only 32%!

More needs to be done for our soldiers.

Most of the CES research shows effects above (in addition to) drug effects.
Cranial Electrotherapy Stimulation (CES)

**Easy 4-Step Procedure:**
1. Wet Electrodes
2. Place on Ear Lobes
3. Turn on CES Device
4. Set to Comfortable Current for 20 Minutes to One Hour

The application of low level current, (usually <1 mA) applied across the head for medical or psychological conditions, or just as an aid in relaxation.

FDA authorized by Rx for anxiety, depression and insomnia.

Also (with or without meds) for fibromyalgia, ADD/ADHD, PTSD, CRPS (RSD), SCI, phantom limb pain, and other pain syndromes.
THE SCIENCE BEHIND CEREBRAL ELECTROSTIMULATION

Daniel L. Kirsch, Ph.D., D.A.A.P.M., F.A.I.S.
with a foreword and preface by Pierre L. Leroy, M.D., F.A.C.S.
and an introduction by Ray B. Smith, Ph.D., M.P.A.

A complete annotated bibliography
The most important
of 126 human and 40 experimental
breakthrough in stress
animal studies, plus 31 reviews and
management for the
2 meta-analyses, a current density model
21st century.
of CES, side effects and follow-up tables,
Discover all the facts inside.
all indexed and cross-referenced.

Second Edition
Experiential Results From CES

Most people report:

- Happier,
- Their Bodies are More Relaxed,
- Their Minds are More Alert,
- and They Feel Younger, More Energetic
Michael Hutchison Author of **Megabrain**
describing his first CES experience:

“My body immediately felt heavier,
as if I was sinking down into myself.
[Then] I realized I was becoming extremely relaxed.

...Things are very, very clear.
My body was no longer heavy, but very light, full of energy.
The feeling was one of openness, clarity,
as though I had been wearing sunglasses for weeks
and had suddenly taken them off.
I couldn’t help but feel that
this is the way we’re supposed to be all the time.”
Dr. Saul H. Rosenthal
Psychiatrist and CES Researcher Reported:

Calm, Relaxed Sensation
Activation of Alertness
Euphoric Tranquility
Not Worrying
Bright and Happy
Increased Energy
Improved Sleep
No Confusion, Memory Loss or Disorientation
“As if I have been given a happy pill. Sort of a floaty, smiley feeling, very pleasant. This is quite a change of moods.”

“Anxiety about capability seems reduced.”

“Smiling for no reason.”

“As though I have almost been conditioned not to worry.”

“Although I feel depressed, it is nothing like I would expect from past experience, even though the problem is large.”
Safety First
CES Contraindications, Precautions, and Adverse Effects

- Interference with pre-1998 implanted devices (e.g., demand type pacemakers) – No longer applicable?
- Pregnancy – possible miscarriage and potential unsubstantiated legal arguments in case of developmental defects
- Skin reactions (redness to burns)
- May cause myogenic, cervicogenic headaches, vertigo, or nausea
- Patients should not drive or operate heavy machinery during or in rare cases after use
- May lower blood pressure in essential hypertension (may have to decrease meds)
Adverse Effects from CES

From 126 human studies encompassing 6,007 people with 4,541 receiving active CES treatment:

- 9 myogenic headaches (0.20%, 1:506)
- 5 cases of skin irritation (0.11%, 1:910)

These are mild and self-limiting.
Primary Contraindications
844 fetal rats had 1 hour/daily CES throughout their pregnancy at 10, 100, or 1,000 Hz, 1 volt, 125 µA via ear tag electrodes.

Autopsy revealed no congenital anomalies.

- More pregnancy resorptions and fewer offspring in all groups, but only significant in the 1,000 Hz group.
- Average fetal weight and brain weight were inversely proportional to frequency.
- Behavior resembled CES in humans, even in this aggressive species; treated rats were not as active as the controls, so the decrease in fetal weights may be because their food intake was lowered.

Conclusion: CES may be embryolethal in the very early stages of pregnancy and might cause some miscarriages, but there is no evidence of fetotoxic effects.
Tracey Kirsch did CES throughout both pregnancies...

(Mrs. Kirsch at 29+)

Gabrielle Electra Kirsch at 3 ½ years

Sasha Kirsch at 4 months!
Traditional Drug-Oriented View of Synapse

But only 2% of neuronal communication occurs at the synapse
Models of Receptor Activation

19th & 20th Century
Chemical/Molecular Physical Communication

21st Century
Physical/Atomic Electromagnetic Communication

Requires random collisions on a hit or miss basis that has little statistical chance of occurring and takes a long time.

An electrical signal with a frequency that perfectly matches the receptor to resonate and activate intracellular responses, even from long distances (like tuning in a radio).
Alpha-Stim CES
Waveform on an Oscilloscope
Alpha-Stim Waveform on a Spectrum Analyzer

Similar to thousands of tuning forks
Therefore, electromedical intervention with the proper variable frequency waveform may act on a receptor in the same way as a drug activating it via a wide range of biological harmonics to send specific messages into cells.
Proposed Mechanisms of CES

James Giordano, PhD
Georgetown University
Beta-endorphins

98% in plasma
219% in cerebral spinal fluid

Serotonin

15 – 40% in plasma
50 – 200% in cerebral spinal fluid

From research by neurosurgeon C. Norman Shealy, MD
QEEG changes in 30 subjects treated with 20 minutes of Alpha-Stim CES. There is an increase in alpha activity with a simultaneous decrease in delta activity. 

Blue = decrease  Red = increase

Courtesy of Richard Kennerly, University of North Texas Ph.D. dissertation
# Results

Achieved with Alpha-Stim Microcurrent Technology Based on a **Physician Survey** of 500 Patients

<table>
<thead>
<tr>
<th>Condition</th>
<th>N</th>
<th>Worse</th>
<th>No Change</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-99%</th>
<th>Complete 100%</th>
<th>Significant &gt;25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>286</td>
<td>1</td>
<td>5</td>
<td>20</td>
<td>48</td>
<td>77</td>
<td>108</td>
<td>27</td>
<td>260</td>
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<tr>
<td></td>
<td></td>
<td>0.35%</td>
<td>1.75%</td>
<td>6.99%</td>
<td>16.78%</td>
<td>26.92%</td>
<td>37.76%</td>
<td>9.44%</td>
<td>90.91%</td>
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<tr>
<td>Anxiety</td>
<td>349</td>
<td>0</td>
<td>8</td>
<td>14</td>
<td>39</td>
<td>89</td>
<td>181</td>
<td>18</td>
<td>327</td>
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<tr>
<td></td>
<td></td>
<td>0.00%</td>
<td>2.29%</td>
<td>4.01%</td>
<td>11.17%</td>
<td>25.50%</td>
<td>51.86%</td>
<td>5.16%</td>
<td>93.70%</td>
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<tr>
<td>Depression</td>
<td>184</td>
<td>0</td>
<td>8</td>
<td>11</td>
<td>31</td>
<td>38</td>
<td>82</td>
<td>14</td>
<td>165</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.00%</td>
<td>4.35%</td>
<td>5.98%</td>
<td>16.85%</td>
<td>20.65%</td>
<td>44.57%</td>
<td>7.61%</td>
<td>89.67%</td>
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<tr>
<td>Stress</td>
<td>259</td>
<td>0</td>
<td>6</td>
<td>12</td>
<td>37</td>
<td>70</td>
<td>124</td>
<td>10</td>
<td>241</td>
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<tr>
<td></td>
<td></td>
<td>0.00%</td>
<td>2.32%</td>
<td>4.63%</td>
<td>14.29%</td>
<td>27.03%</td>
<td>47.88%</td>
<td>3.86%</td>
<td>93.05%</td>
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<td>Insomnia</td>
<td>135</td>
<td>0</td>
<td>16</td>
<td>12</td>
<td>17</td>
<td>34</td>
<td>45</td>
<td>11</td>
<td>107</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.00%</td>
<td>11.85%</td>
<td>8.89%</td>
<td>12.59%</td>
<td>25.19%</td>
<td>33.33%</td>
<td>8.15%</td>
<td>79.26%</td>
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<tr>
<td>Headache</td>
<td>151</td>
<td>1</td>
<td>8</td>
<td>6</td>
<td>25</td>
<td>32</td>
<td>63</td>
<td>16</td>
<td>136</td>
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<tr>
<td></td>
<td></td>
<td>0.66%</td>
<td>5.30%</td>
<td>3.97%</td>
<td>16.56%</td>
<td>21.19%</td>
<td>41.72%</td>
<td>10.60%</td>
<td>90.07%</td>
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<tr>
<td>Muscle Tension</td>
<td>259</td>
<td>2</td>
<td>6</td>
<td>6</td>
<td>42</td>
<td>76</td>
<td>111</td>
<td>16</td>
<td>245</td>
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<tr>
<td></td>
<td></td>
<td>0.77%</td>
<td>2.32%</td>
<td>2.32%</td>
<td>16.22%</td>
<td>29.34%</td>
<td>42.86%</td>
<td>6.18%</td>
<td>94.59%</td>
</tr>
</tbody>
</table>

**Depression:** 73% >50% or 52% >75% improved

**Pain:** 74% >50% or 47% >75% improved
## Results Achieved with Alpha-Stim Technology

### Based on a Survey of Patients Reporting Psychological Disorders

<table>
<thead>
<tr>
<th>Condition</th>
<th>N*</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-100%</th>
<th>Significant &gt;25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological (all cases)</td>
<td>723</td>
<td>61</td>
<td>175</td>
<td>237</td>
<td>250</td>
<td>662</td>
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<tr>
<td></td>
<td></td>
<td>8.44%</td>
<td>24.20%</td>
<td>32.78%</td>
<td>34.58%</td>
<td>91.56%</td>
</tr>
<tr>
<td>Anxiety (alone)</td>
<td>128</td>
<td>13</td>
<td>29</td>
<td>42</td>
<td>44</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.16%</td>
<td>22.66%</td>
<td>32.81%</td>
<td>34.38%</td>
<td>89.84%</td>
</tr>
<tr>
<td>Anxiety (with other)</td>
<td>370</td>
<td>33</td>
<td>85</td>
<td>122</td>
<td>130</td>
<td>337</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8.92%</td>
<td>22.97%</td>
<td>32.97%</td>
<td>35.14%</td>
<td>91.08%</td>
</tr>
<tr>
<td>Anxiety/Depression</td>
<td>58</td>
<td>3</td>
<td>19</td>
<td>19</td>
<td>17</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.17%</td>
<td>32.76%</td>
<td>32.76%</td>
<td>29.31%</td>
<td>94.83%</td>
</tr>
<tr>
<td>Depression (alone)</td>
<td>53</td>
<td>7</td>
<td>11</td>
<td>23</td>
<td>12</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13.21%</td>
<td>20.75%</td>
<td>43.40%</td>
<td>22.64%</td>
<td>86.79%</td>
</tr>
<tr>
<td>Depression (with other)</td>
<td>265</td>
<td>29</td>
<td>61</td>
<td>93</td>
<td>82</td>
<td>236</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.94%</td>
<td>23.02%</td>
<td>35.09%</td>
<td>30.94%</td>
<td>89.06%</td>
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<tr>
<td>Stress</td>
<td>123</td>
<td>6</td>
<td>30</td>
<td>39</td>
<td>48</td>
<td>117</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.88%</td>
<td>24.39%</td>
<td>31.71%</td>
<td>39.02%</td>
<td>95.12%</td>
</tr>
<tr>
<td>Chronic Fatigue</td>
<td>50</td>
<td>3</td>
<td>30</td>
<td>10</td>
<td>7</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.00%</td>
<td>60.00%</td>
<td>20.00%</td>
<td>14.00%</td>
<td>94.00%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>163</td>
<td>10</td>
<td>47</td>
<td>47</td>
<td>59</td>
<td>153</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.13%</td>
<td>28.83%</td>
<td>28.83%</td>
<td>36.20%</td>
<td>93.87%</td>
</tr>
</tbody>
</table>

*Total N = 2500 patients with multiple symptoms. Results of those using Alpha-Stim™ at least 3 weeks before mailing warranty card. Warranty cards are 2500 consecutive cards received as of July 2000.

### Depression: 66% >50% or 23 - 31% >75% improved
Research Methodology of
86 Pivotal (out of 126) Studies of CES

35  Double-Blind Placebo-Controlled
9   Single-Blind
15  Controlled Study
6   Crossover
22  Open Clinical Trial
2   Retrospective Study
3   Case Study
13  Follow-up
HOW WE DOUBLE-BLIND CES

- Decrease current to a subsensory level of 100 µA by oscilloscope.
- Increase time to 1 hour to compensate for the reduced current dose.
- The frequency is set to 0.5 Hz.
- Half the wires are non-conducting.
- The controls are taped over so only the power-on button and battery compartments are accessible.
- Serial numbers are then randomized as per protocol (researchers must record SN for each subject to know if device is active or sham).
Topics of Scientific Research on CES

CES is FDA approved for anxiety, depression, and insomnia

Number of Pivotal Scientific Studies:

42 Anxiety + 1 Phobia
26 Depression
27 Insomnia
10 stress
Outcomes of Cranial Electrotherapy Stimulation (CES) with Soldiers for Combat-related Symptoms
Brooke Army Medical Center (BAMC)

β LTC Mona O. Bingham, LTC, AN
β Alice W. Inman, Psy.D, GS 12, USA

IRB approved – in progress
Effect of CES on PTSD in Burned Outpatients USAISR

Elizabeth A. Mann, MAJ, AN
Alfredo Montalvo, LTC, AN
Kathryn Gaylord, COL, AN
Scott Dewey, PT, CHT, OCS
Reg Richard, MS, PT
Travis Hedman, CPT, SP

IRB approved – in progress
Two Meta-Analyses Confirmed the Significance of CES Research for Treating Anxiety:

♦ **University of Tulsa** (O’Connor, Presented at the 12th annual meeting of the Bioelectromagnetics Society, 1991)


Both Found CES Significantly Effective for Anxiety (P<.05)
Meta-Analysis of CES for Anxiety

- 40 Studies
- r Effect Size = .58
- 17 Double Blind Studies, r = .53

- Effect sizes of r = .44 to r = .70 would be expected to be found in the next 99 out of 100 meta-analyses of CES for anxiety

- R effect size = % improvement based on 100%
- Scale: .10 is small, .30 is moderate, .50+ is considered high
Change in Stress Measures from a Single Alpha-Stim CES Treatment

Heffernan, 1995
Situational Anxiety in Dentistry
Following Real or Sham Alpha-Stim CES Treatment

Winick, 1999

Graph showing Visual Analogue Scale Anxiety Score before and after treatment with Alpha-Stim or Sham treatment. The graph indicates a decrease in anxiety scores post-treatment for both groups, with a more significant decrease for the Alpha-Stim treated group.
Response of Anxious Parolees to Alpha-Stim CES

Voris, 1995
Treating Sexual Offenders for 6 Weeks with Alpha-Stim CES or Relaxation Training

Voris and Good, 1996

---

**Trait Anxiety Stress Measure Used:**
- Electromyogram

**Percent Improvement:**
- CES Anxiety
- Relaxation Group Anxiety
- CES/Electromyogram
- Relaxation Group/Electromyogram

---

**Stress Measure Used:**
- Trait Anxiety
- Electromyogram
Improvement of Stress Measures in 182 Anxious Patients Following 9, 25 Minute Alpha-Stim Treatments

% Improvement

Temperature | Electrodermal | Anxiety Scale | Electromyogram

Stress Related Measure

Overcash, 1999
Percent Increase in Relaxation Response of 8 Horses Following 20 minutes of Alpha-Stim Treatment

Clark, Mills and Marchant, 2000

- Heart Rate, 17%
- Standing Alert, 20%
- Dozing, 384%
- Shaking Head, 46%
- Vocalizing, 25%
- Ear Flicking, 42%
Attention Deficit Disorder (ADD)

Smith, 1999

Graph showing percent improvement for various tests:
- Depression
- State Anxiety
- Trait Anxiety
- Verbal I.Q.
- Performance I.Q.
- Full Scale I.Q.

Tests include:
- Emotional and Cognitive Tests
- Percent Improvement

Graph data indicates significant improvement in Depression, State Anxiety, Trait Anxiety, Verbal I.Q., Performance I.Q., and Full Scale I.Q.
The Impact of CES on Learning Psychomotor Tasks
Madden and Kirsch, 1987

Cumulative Percent Improvement

Sham Treated
CES Treated

Base Level
2nd Trial
3rd Trial
4th Trial
Meta-Analysis of CES for Depression

- 20 Studies
- r Effect Size = .50
- 9 Double Blind Studies

- Effect sizes of r = .32 to r = .68 would be expected to be found in the next 99 out of 100 meta-analyses of CES for depression

- R effect size = % improvement based on 100%
- Scale: .10 is small, .30 is moderate, .50+ is considered high
CES Review: A Safer Alternative to Psychopharmaceuticals in the Treatment of Depression
Marshall Gilula, MD and Daniel L. Kirsch, PhD


![Chart showing percent improvement over placebo for different treatments](chart.png)

- CES is 3x more efficacious than the average SSRI
The Effects of 7 to 10 Days of CES Treatments on Depression

4 Studies

Percentile on Depression Scale Norms

Zung Depression Scale

After CES Treatment
Before CES Treatment
The Effects of 2 and 3 Weeks of CES Treatments on Depression

5 Studies

Percentile on Depression Scale Norms

After CES Treatment
Before CES Treatment

POMS Depression Scale

1 2 3 4 5
Meta-Analysis of CES for Insomnia

- 20 Studies
- r Effect Size = .64
- 7 Double Blind Studies

- Effect sizes of r = .41 to r = .87 would be expected to be found in the next 99 out of 100 meta-analyses of CES for insomnia

- R effect size = % improvement based on 100%
- Scale: .10 is small, .30 is moderate, .50+ is considered high
CES Double-Blind Fibromyalgia Study
Rheumatology

Lichtbroun et al. 2001 (N=60)

Sleep Pattern of Study Groups

- Little or No Sleep
- Moderate Sleep
- Good, Very Restful Sleep

Group Reporting

- Pre Study
- Sham Rx
- Subsensation CES
- Sensate CES

Percent in Each Sleep Category

0 10 20 30 40 50 60 70
much of the early research was in substance abuse populations

Topics of Scientific Research on CES

Number of Pivotal Scientific Studies:

14 alcohol
1 cigarette
3 cocaine
2 heroin
2 marijuana
3 methadone
3 opiates
9 polysubstance abuse
8 withdrawal
The Effect of Adding Alpha-Stim CES to a Marijuana Drug Treatment Program

Overcash and Siebenthall, 1989
CES in the Treatment of Cocaine Addiction

Brovar, 1984

<table>
<thead>
<tr>
<th>Condition Measured</th>
<th>CES Treated</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Completing Detox</td>
<td>100</td>
<td>80</td>
</tr>
<tr>
<td>% Completing Treatment</td>
<td>100</td>
<td>60</td>
</tr>
<tr>
<td>% Not Recidivating in 8 Months</td>
<td>70</td>
<td>40</td>
</tr>
</tbody>
</table>
Methadone Self Withdrawal Study

Gomez and Mikhail, 1979
Dr. Brad May

Comments from Alcoholic Patients:

“Something inside me has shifted and I just know I’m never going to take another drink of alcohol again.”

“I’ve been sober for about 75 days, but it feels like I’ve been sober for years.”
The Use of CES to Potentiate Anesthesia in Surgery

Watch Meds! Decrease Dosage by 1/3 to 1/2

The Use of CES to Potentiate Anesthesia in Surgery

4 Studies

Amount of Anesthetic Required

Fentanyl
N₂O 50%
N₂O 62.5%
N₂O 75%

Anesthetic Used

Anesthesia Plus CES
Anesthesia Alone
Tail Flick Latency (TFL) studies Revealed a significant increase in analgesic effect of opiates. (Stinus, 1990).

<table>
<thead>
<tr>
<th>Drug</th>
<th>TFL as % of baseline</th>
<th>Drug Alone</th>
<th>Drug + CES</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td>174%</td>
<td>306%</td>
<td></td>
</tr>
<tr>
<td>fentanyl</td>
<td>176%</td>
<td>336%</td>
<td></td>
</tr>
<tr>
<td>alfentanil</td>
<td>160%</td>
<td>215%</td>
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<tr>
<td>dextromoramide</td>
<td>267%</td>
<td>392%</td>
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Results were also obtained after intracerebroventricular injection of 10 micrograms of morphine: **analgesic effect increased from 152% to 207% with CES.** Suggestis potentiation of opiate-induced analgesia is centrally mediated.
# Topics of Scientific Research on CES

## Number of Pivotal Scientific Studies:

<table>
<thead>
<tr>
<th>for brain functions</th>
<th>pain</th>
<th>and other applications</th>
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</thead>
<tbody>
<tr>
<td>attention deficit disorder (ADD)</td>
<td>4 anesthesia</td>
<td>2 bronchial asthma</td>
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<tr>
<td>cerebral palsy</td>
<td>3 dental</td>
<td>1 gastric acidity</td>
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<tr>
<td>closed head injuries</td>
<td>2 fibromyalgia</td>
<td>1 labor</td>
</tr>
<tr>
<td>cognitive dysfunction</td>
<td>5 headaches</td>
<td>2 sex offenders</td>
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<tr>
<td>learning and memory</td>
<td>8 muscle tone/movement/tremor</td>
<td>3 suggestibility</td>
</tr>
<tr>
<td>reaction time, vigilance</td>
<td>13 pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 rehabilitation</td>
<td></td>
</tr>
</tbody>
</table>
Migraine Headaches -- Frequency and Intensity

Following 8 Treatments

After 1 Month
After 2 Months
After 3 Months

Accumulated Percent Improvement

Time After Treatment Began

Biofeedback Alone
Biofeedback Plus CES

Brotman, 1989
Example of the CES Response in a Patient with Severe Migraine

Courtesy of COL Michael Singer (retired), Walter Reed Army Medical Center

Stay with it!
Cumulative Responses to 1st and 2nd 20 Minute CES Pain Treatments, N = 174
Treating Spinal Cord Injury Pain with Cranial Electrotherapy Stimulation
CTan, PhD1,2 DH Rinaldi, PhD3 J Thornby, PhD1 J Yang, MD3 WH Wade, MD1,2 C Vasilescu1
1,2Michael E. DeBakey Veterans Affairs Medical Center, 3Baylor College of Medicine, Dept. of PM&R
3Washington, DC Veterans Affairs Medical Center, *University of Texas M. D. Anderson Cancer Center

INTRODUCTION
Chronic pain is a major problem following spinal cord injury (SCI) and a major component to unsuccessful rehabilitations. Cranial electrotherapy stimulation (CES) has been shown to “normalize” abnormal pain responses, change the hypothalamic-pituitary-adrenal axis, increasing GABA production, and bring neurotransmitters in neural systems to normal levels of homeostasis. Recent studies have shown CES to be effective in reducing pain and enhancing quality of life of chronic pain sufferers with a number of pain conditions, including thoracicgia, which has a centrally-mediated pain component. A pilot study was undertaken to assess the effectiveness of CES in persons with SCI.

CHARACTERISTICS OF THE SAMPLE

PROCEDURE
1. Recruit veterans with SCI known to have pain from the Michael E. DeBakey Veterans Affairs Medical Center (MEVAMC) SCI registry via telephone
2. Obtain informed consent and pre-treatment data in person at the MEVAMC (see measures below)
3. Pair each participant’s worst pain (study target pain), a physician determined whether it was acceptable or unacceptable
4. Trained participants in the use of the cranial electrotherapy device and daily pain rating sheet
5. Randomized (double-blind) participants into Shaw and Active groups
6. Participants used the device one hour per day for 14 consecutive days and completed the Daily Pain Rating Sheet before and after each session
7. Contacted participants weekly by telephone to ensure compliance, identity and other protocol modifications, and ensured proper use
8. Collected pre-treatment data in person at the MEVAMC and collected the device and the daily pain rating sheet
9. Provided a supervised device to each group to use for another 14 days, which allowed participants to adjust the level of stimulation
10. Collected pre- and post-data from each group in person at the MEVAMC and collected the device and the daily pain rating sheet

MEASURES
1. Demographic information
2. Level and consistency of pain from medical record
3. Brief Pain Inventory (BPI) – Pain Intensity and Pain Interference scales
4. Daily Pain Rating Sheet – Numeric pain intensity on 0–10 scale before and after each daily session

RESULTS

COMPOSITE PAIN INTENSITY (0 TO 40 SCALE) AND PAIN INTERFERENCE SCORES (0 TO 100 SCALE)

DEVICE
1. AlphaStim® Cranial Electrotherapy Stimulator
2. Treatment group received 100 minutes of sham-stimulation cranial electrotherapy stimulation (CES)
3. Device for sham group delivered no CES

CONCLUSIONS
Based on reported pain reduction pre and post each session, the Active CES treatment was found to be significantly more effective than the Sham treatment with a moderate to large effect size (Cohen’s d = .76). Future studies will be needed to evaluate the long-term effectiveness of CES.
Figures 1, 2, and 3: Daily Pain Rating for Active CES and Sham CES Groups
Improvement in a TBI/RSD Patient Following Alpha-Stim CES Treatment

Alpher and Kirsch, 1998
Alpha-Stim CES DB Fibromyalgia Study
Rheumatology

Lichtbroun et al. 2001 (N=60)
CES Double-Blind Fibromyalgia Study
LSU Dept of Anesthesiology

Cork et al. 2004 (N = 74)

Pain Intensity (0-5)

- *p<0.01 between Groups
- **p<0.001 from Baseline

Mean±Standard Error

Baseline

3 Weeks
Double-Blind

6 Weeks
Sham/CES Crossover

Sham Group
CES Group
CES Double-Blind Fibromyalgia Study
LSU Dept of Anesthesiology

Cork et al. 2004 (N = 74)

POMS Score

* \( p < 0.01 \) between Groups
** \( p < 0.001 \) from Baseline
Comments on Follow-up from all CES Research Studies

FROM PIVOTAL SCIENTIFIC STUDIES:

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>N</th>
<th>Subject Description</th>
<th>Authors’ Comments on Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brotman, Philip</td>
<td>1986</td>
<td>36</td>
<td>classical migraine pts</td>
<td>CES group responded significantly better than the other 2 groups over the <strong>3 month</strong> follow-up.</td>
</tr>
<tr>
<td>Brovar, A.</td>
<td>1984</td>
<td>25</td>
<td>cocaine abusers</td>
<td>No CES patients had returned for treatment, while 50% of the CES refusers and 39% of the controls recidivated in <strong>6 to 8 months</strong>.</td>
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<tr>
<td>Flemenbaum, A.</td>
<td>1974</td>
<td>28</td>
<td>anxiety, depression, insomnia outpatients unresponsive to medication</td>
<td>Those who had beneficial results maintained them throughout the <strong>6 month</strong> follow-up.</td>
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<tr>
<td>Hearst, E.D.</td>
<td>1974</td>
<td>28</td>
<td>psychotherapy outpatients</td>
<td>3 patients showed continued improvement for <strong>2 weeks to 2 months</strong>.</td>
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<tr>
<td>Study</td>
<td>Participants</td>
<td>Follow-up Measures</td>
<td>Results</td>
<td></td>
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<tr>
<td>------------------</td>
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<tr>
<td>Heffernan, Michael 1995</td>
<td>20 stress pts &gt;1 year, unresponsive to medication</td>
<td>1 week follow-up measures in the CES group showed significant carryover effects in EMG and HR</td>
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<tr>
<td>Magora, F. 1967</td>
<td>A: anxiety, depression, insomnia hospitalized polysubstance abusers, and B: asthmatic children unresponsive to medication</td>
<td>A: Follow-up has continued for 8-12 months after treatment and has revealed no relapse. B: The asthmatic attacks stopped completely in 3 children and 4 months later the children felt well without taking any drugs.</td>
<td></td>
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<tr>
<td>Matteson, Michael 1986</td>
<td>32 CES graduate students, 22 controls</td>
<td>A follow-up measure 2 weeks post study found that 11 of the 13 variables were still significantly improved in the treatment group.</td>
<td></td>
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<tr>
<td>Moore, J.A. 1975</td>
<td>17 anxiety and insomnia pts</td>
<td>a remarkable improvement” in their symptoms 2 - 3 weeks after CES.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Sample Size</td>
<td>Diagnosis</td>
<td>Follow-up Duration</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Overcash, Stephen</td>
<td>1999</td>
<td>197</td>
<td>anxiety outpatients</td>
<td>6 - 8 month</td>
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<tr>
<td>Patterson, M.</td>
<td>1984</td>
<td>186</td>
<td>hospitalized alcohol and polysubstance abusers</td>
<td>1 to 8 years</td>
</tr>
<tr>
<td>Smith, Ray</td>
<td>1999</td>
<td>23</td>
<td>psychiatric outpatients with anxiety, depression, ADD</td>
<td>18 month</td>
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<tr>
<td>Weiss, Marc</td>
<td>1973</td>
<td>10</td>
<td>insomnia patients</td>
<td></td>
</tr>
</tbody>
</table>
First Year Cost Comparison
Alpha-Stim SCS CES Device vs. SSRI Drugs
Breakeven at 4 to 6 Months
(5-Year SCS Warranty and Assuming No Drug Price Increases)
Summary

- CES is safe
- CES is easy to use
- CES is proven effective
- CES works quickly and lasts
- CES research can be double-blinded
- CES is FDA and DoD/VA approved
- CES is available to help people NOW!
Are Your Patients in Pain?
Having Difficulty Sleeping?
Depressed? Anxious? Stressed?

Why Not Try CES?

Questions? Email: dan@epii.com
Call: 1-800-FOR-PAIN
Chat: www.alpha-stim.com