The Management of Anxiety, Insomnia, Depression and Pain with Cranial Electrotherapy Stimulation (CES) and Microcurrent Electrical Therapy (MET): Theory and Practice

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Director of Science and Education

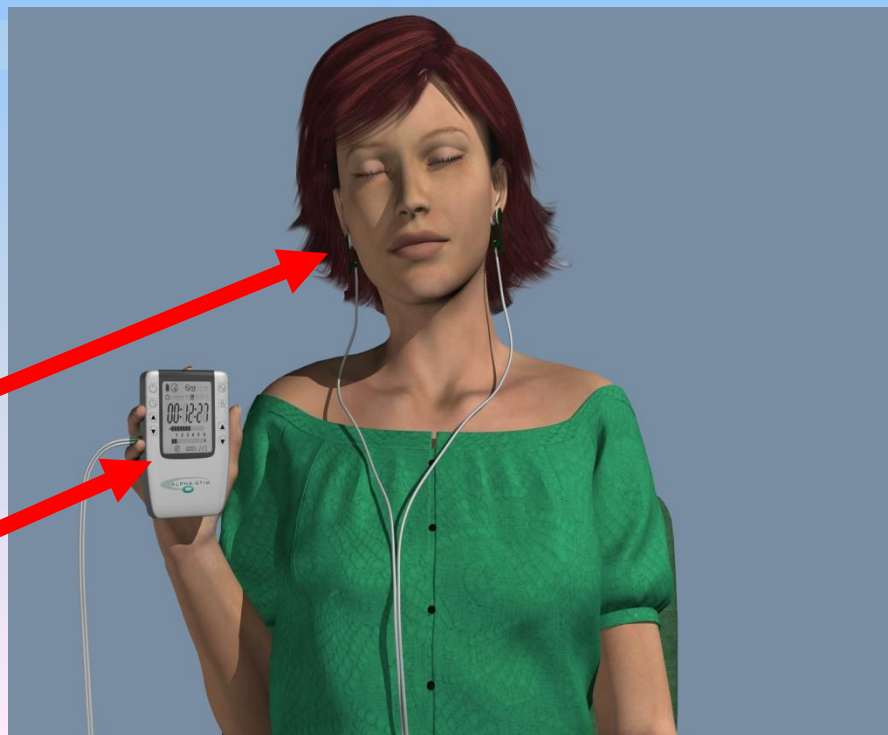
Cranial Electrotherapy Stimulation (CES)

The application of low/tiny level current of <1 milliampere applied across the head. CES is **(legally labeled)** for treatment of anxiety (including PTSD), depression and insomnia. Also used for centrally mediated pain syndromes.

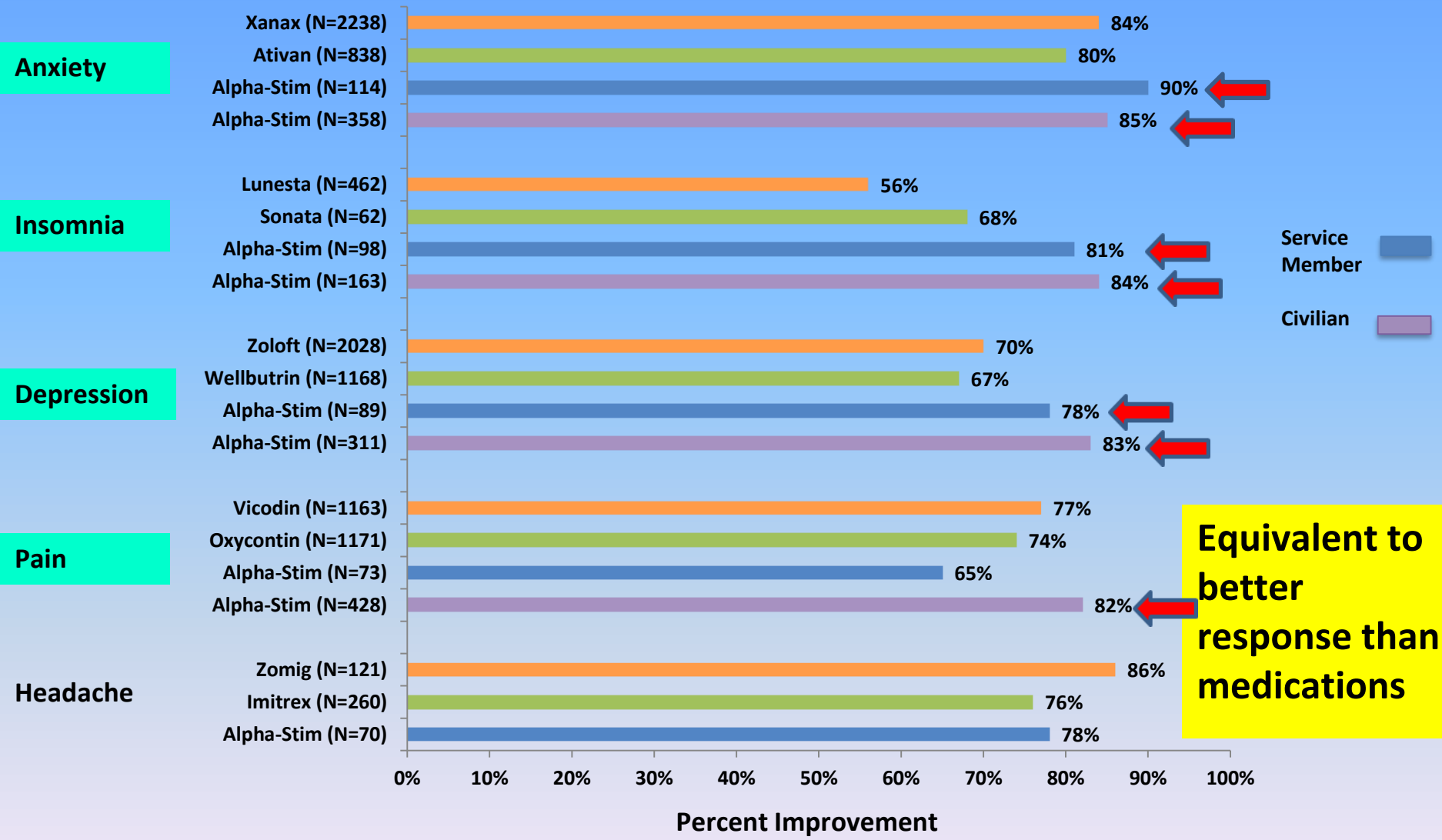
CES not much harder than taking two pills

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



Patients that Reported A Positive Response According to: WebMD Drug Surveys, Alpha-Stim Military and Civilian Surveys 2011.

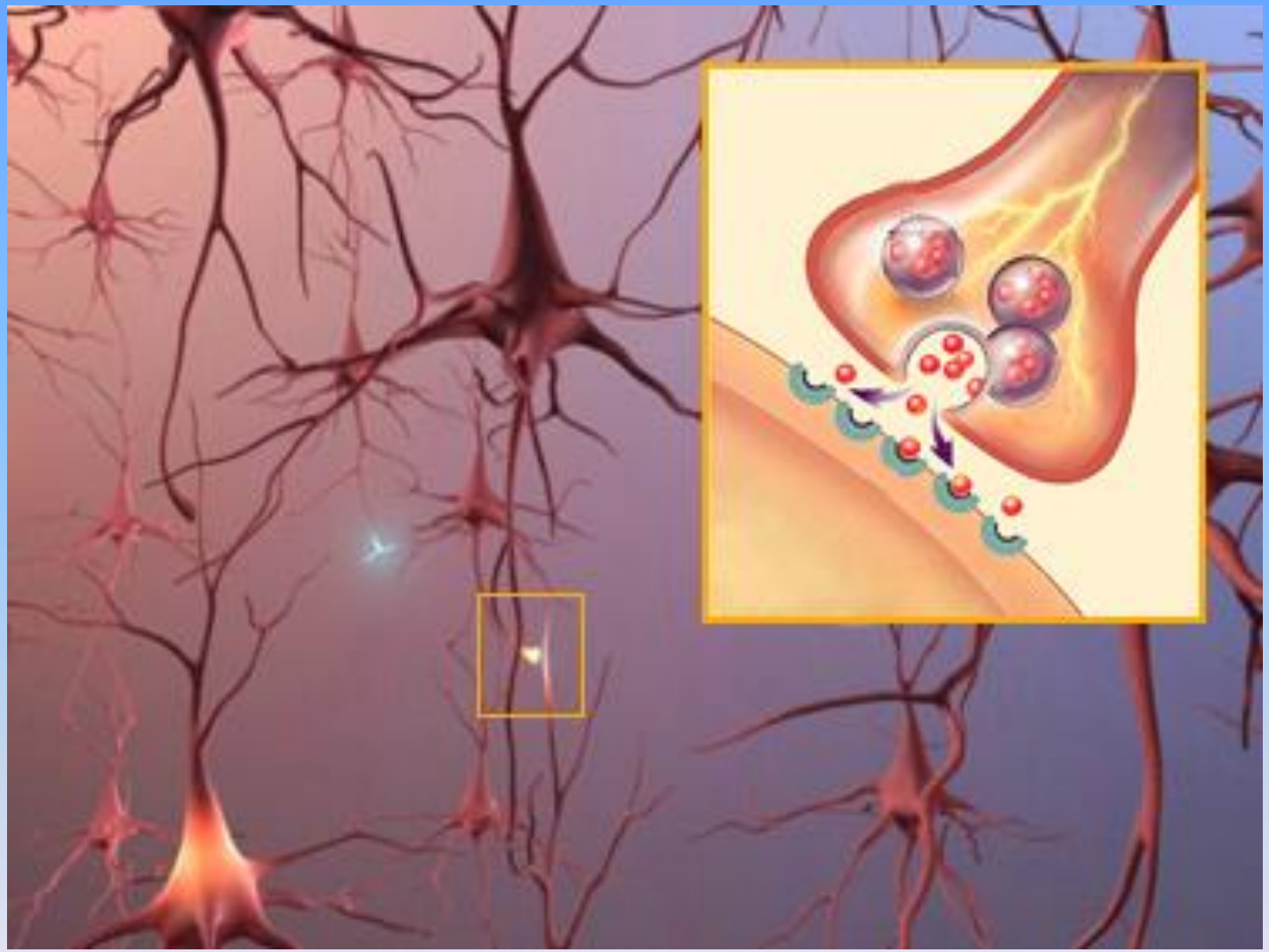


Equivalent to better response than medications

Alpha-Stim Data from October 2011 Military Service Member Survey Analysis (N=152) and Alpha-Stim Patient Survey (N=1,745) October 2011 Conducted by Larry Price PhD, Associate Dean of Research and Professor of Psychometrics and Statistics, Texas State University.

Pharmaceutical Survey Data from: www.WebMD.com/drugs. Accessed on October 28th, 2011.

Traditional View of Synaptic Activity

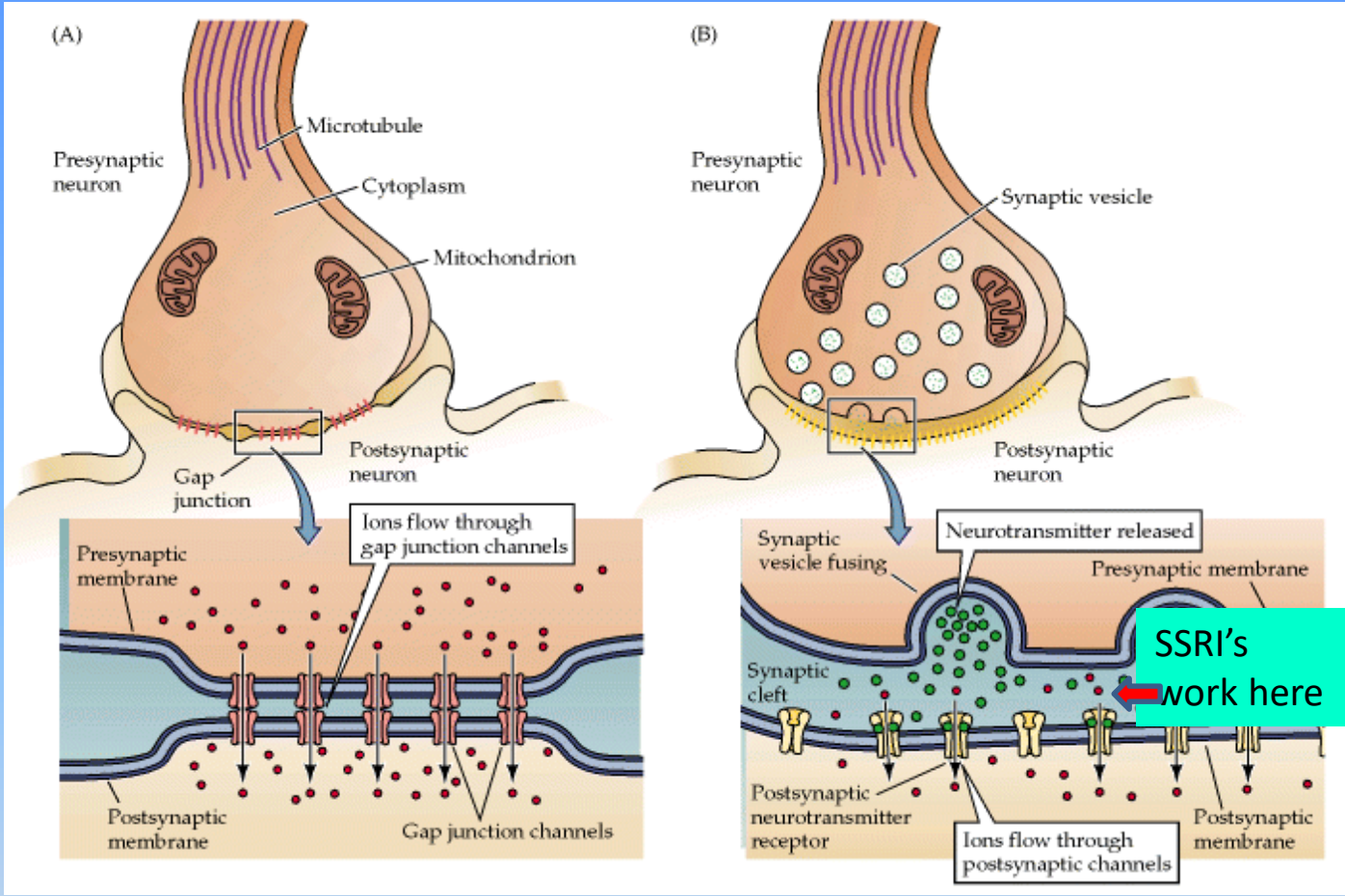


But only 2% of neuronal communication occurs at the chemical synapse.

Pert, Candace. Molecules of Emotion: Why You Feel The Way You Feel. Scribner, New York, 1997.

Electrical and chemical synapses differ fundamentally in their transmission mechanisms

98% of brain communication is electrical only 2% is chemical

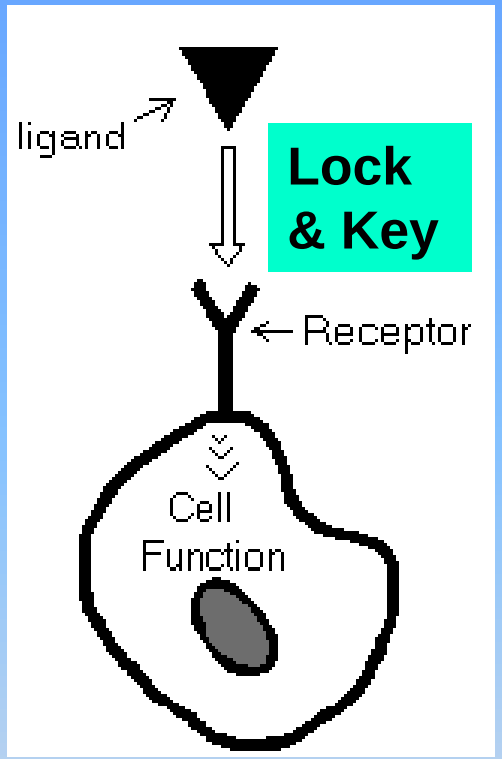


(A) Gap junctions between pre- and postsynaptic membranes permit current to flow passively through intercellular channels. This current flow initiates or inhibits the generation of postsynaptic action potentials.

(B) There is no intercellular continuity, and thus no direct flow of current from pre- to postsynaptic cell. **Current can only flow across the postsynaptic membrane in response to the secretion of neurotransmitters which open or close postsynaptic ion channels after binding to receptor molecules.**

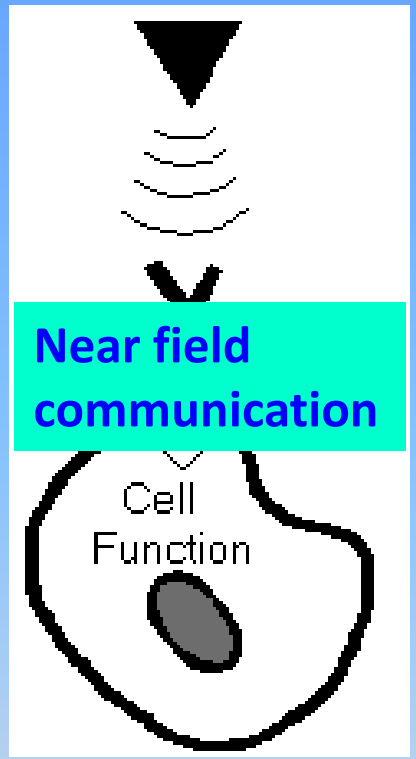
Purves, Dale and Augustine, George J. et al. Neuroscience, 2nd Ed. Sinauer, Sunderland, MA , 2001.

Old and New Models of Receptor Activation



19th & 20th Century

The Old Theory: Structural Matching; Chemical/ Molecular Physical Communication



21st Century

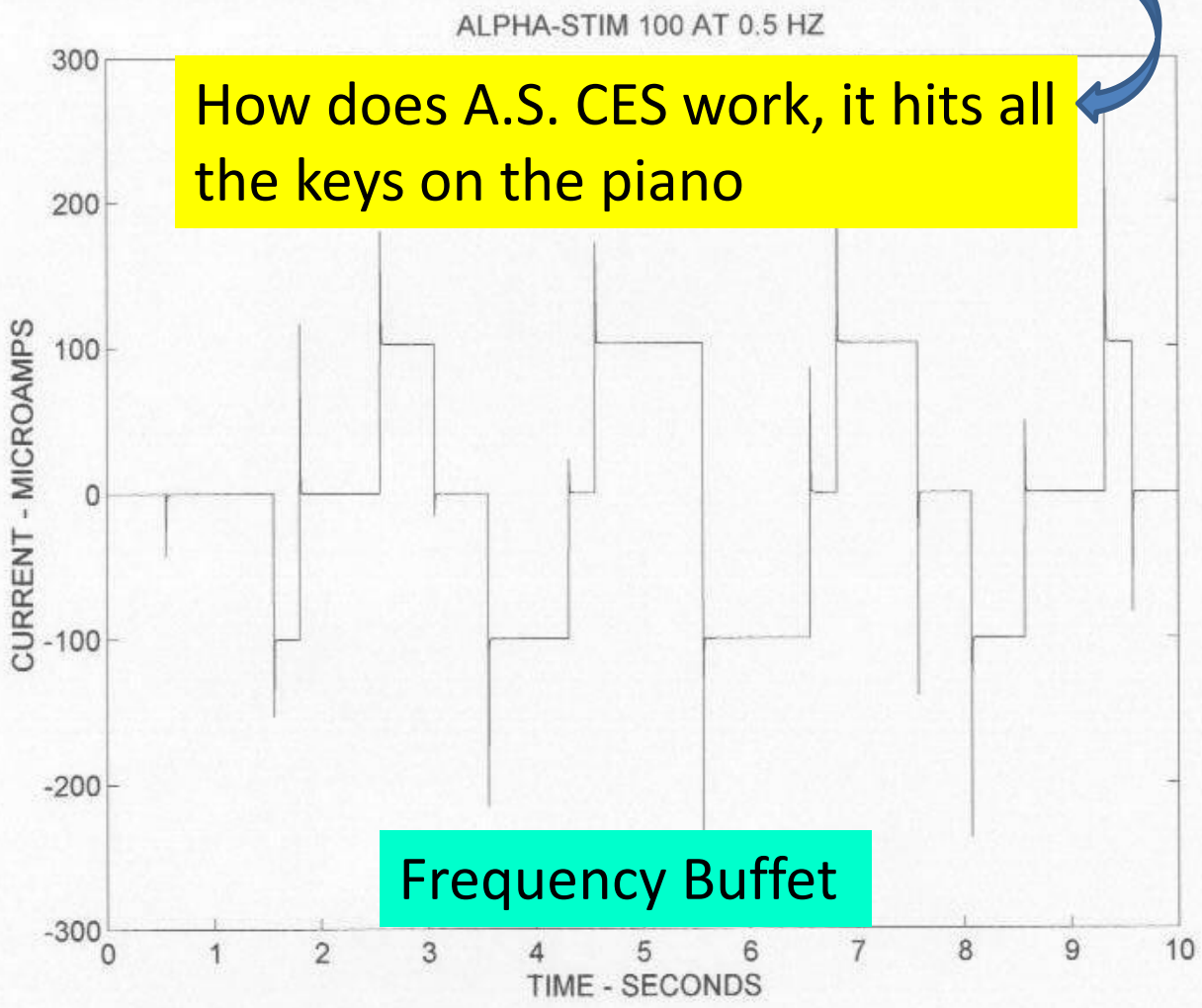
The New Theory: Physical/ Atomic Electromagnetic Communication

The 3D nature of the ligand matches the receptor. Physical proximity induces receptor conformational changes which triggers the cascade of events prompting cell function.

Proximity favors co-resonance of specific bioelectrical signals with frequencies that perfectly match the resonance of the receptor to amplify molecular conformational changes at all steps of the cascade prompting cell function, even from long distances (like tuning in a radio).

Benveniste, J. A fundamental basis for the effects of EMFs in biology and medicine: The interface between matter and function. Chapter 13 in Bioelectromagnetic Medicine. Rosch, P and Markov, M, eds. Marcel Dekker, New York, 2004.

Alpha-Stim® Waveform On Oscilloscope



It is the waveform that differentiates devices.

Through periodic, but slow, reversal of the polarization of the DC current, this patented CES and MET waveform is able to inject a spectrum of low frequencies into neurons to match frequencies with different receptors, thus activating them in a way similar to chemical ligands.

This mechanism is based on the theory that receptors can select the correct exogenous signal they need to send their message into cells.

Cell membrane proteins that protrude from the cells act as molecular chemical receptors and electromagnetic or electric field antennas (Adey, 1988).

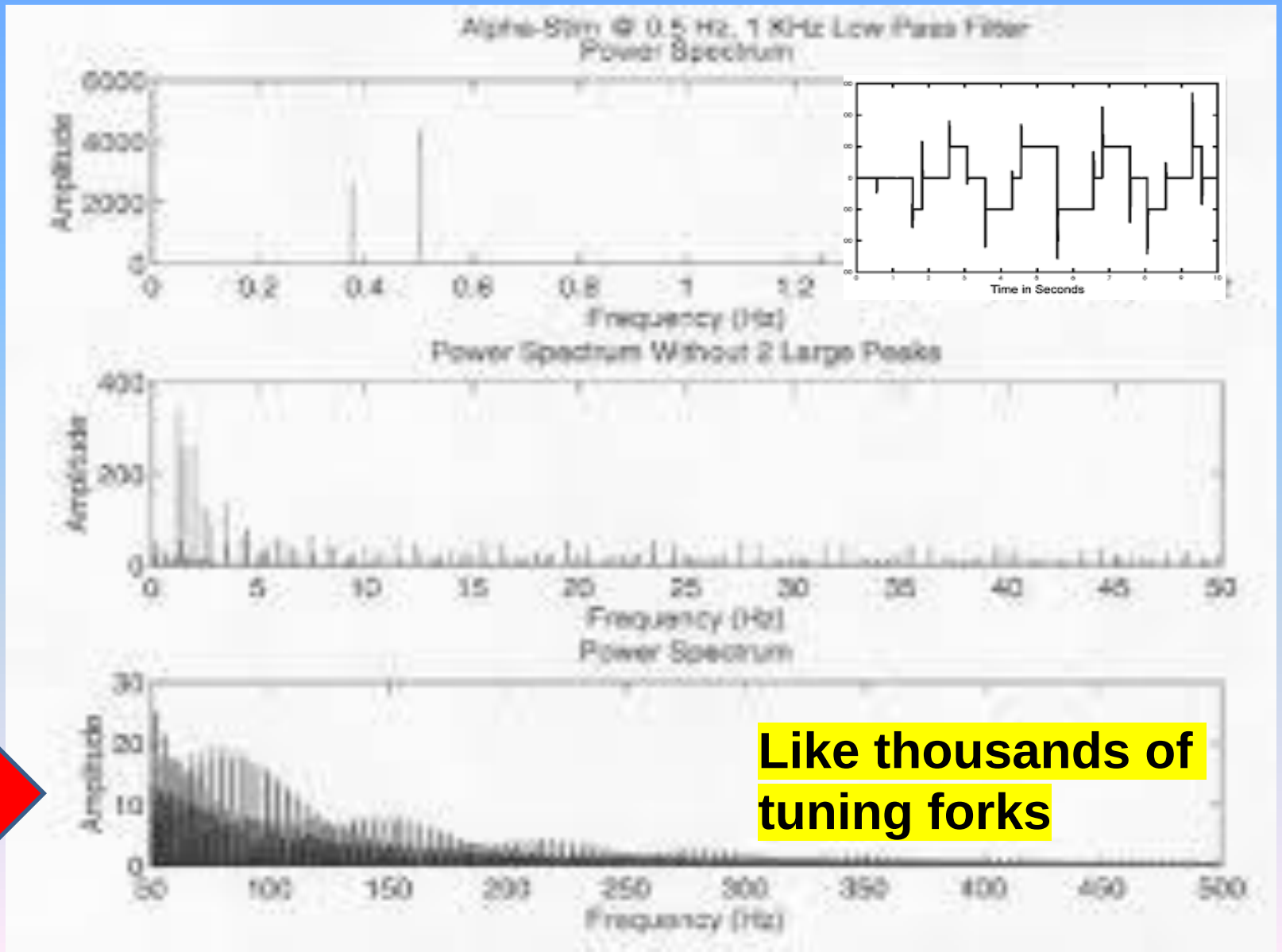
"If fields can affect enzymes and cells, [one should expect] to be able **to tailor a waveform** as a **therapeutic agent** in much the same way as one now modulates chemical structures to obtain pharmacological selectivity and perhaps withhold many of the side-effects common to pharmaceutical substances (Davey and Kell, 1990)."

EMF Antennas

Adey WR. Physiological signaling across cell membranes and cooperative influences of extremely low frequency electromagnetic fields. In: Biological Coherence and Response to External Stimuli, H. Frohlich, ed., Heidelberg, Springer-Verlag, pgs.148-170, 1988.

Davey CL, Kell DB. The dielectric properties of cells and tissues: What can they tell us about the mechanisms of field/cell interactions? In: O'Connor ME, Bentall RHC, Monahan JC, eds. Emerging Electromagnetic Medicine. New York, NY:Springer-Verlag, 1990:19-43.

You start with 0.5 Hz, but due to the waveform you get all the frequencies. It's the harmonics!

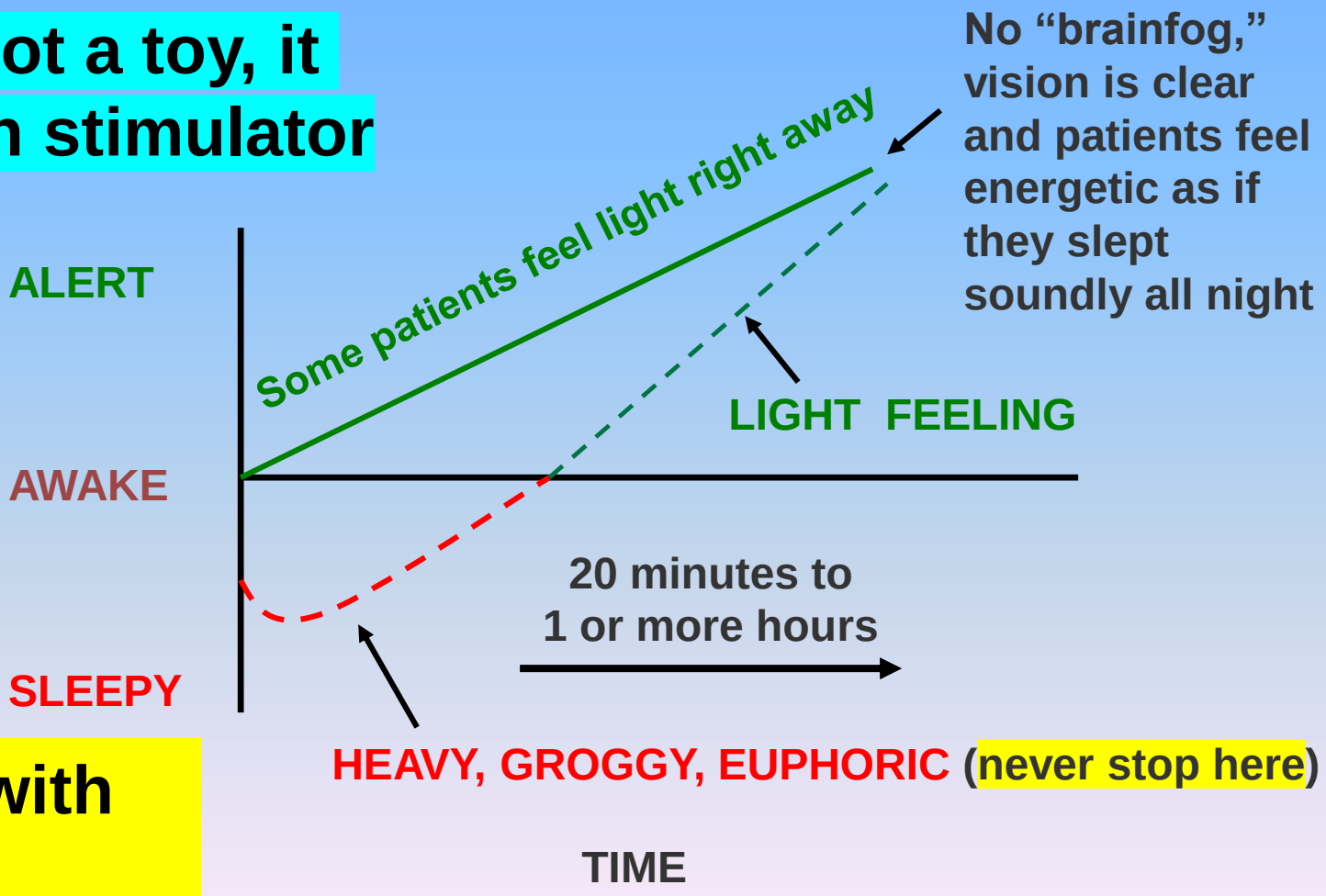


Feelings Experienced During CES Treatment Stages

Dosage equals time inversely proportional to current level.

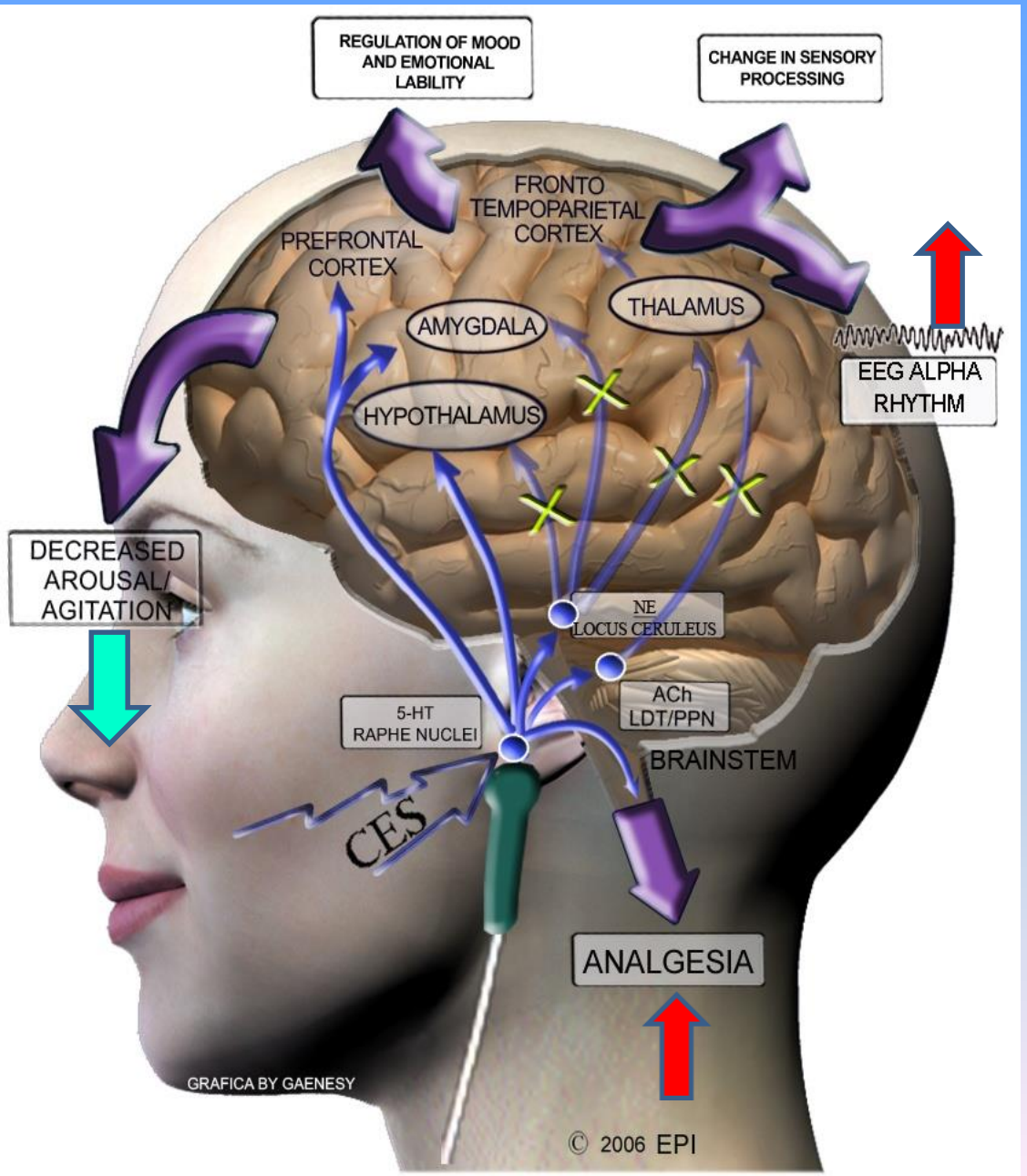
Therefore, less current requires longer treatment time per session.

CES is not a toy, it is a brain stimulator



Treat it with respect

Putative Mechanism of CES



With ear clips the current travels all over the brain stimulating some pathways and inhibiting others

No, purple arrows do not shoot out of the head

1. **EEG changes occur**
2. **Analgesia produced by increase in endorphins**
3. **Serotonin pathways activated**
4. **Reduces excessive cortical activation**

Giordano, James. Illustrating how CES works. Insert in Kirsch, Daniel L. Cranial electro-therapy stimulation for the treatment of anxiety, depression, insomnia and other conditions. *Natural Medicine*, 23:118-120, 2006.

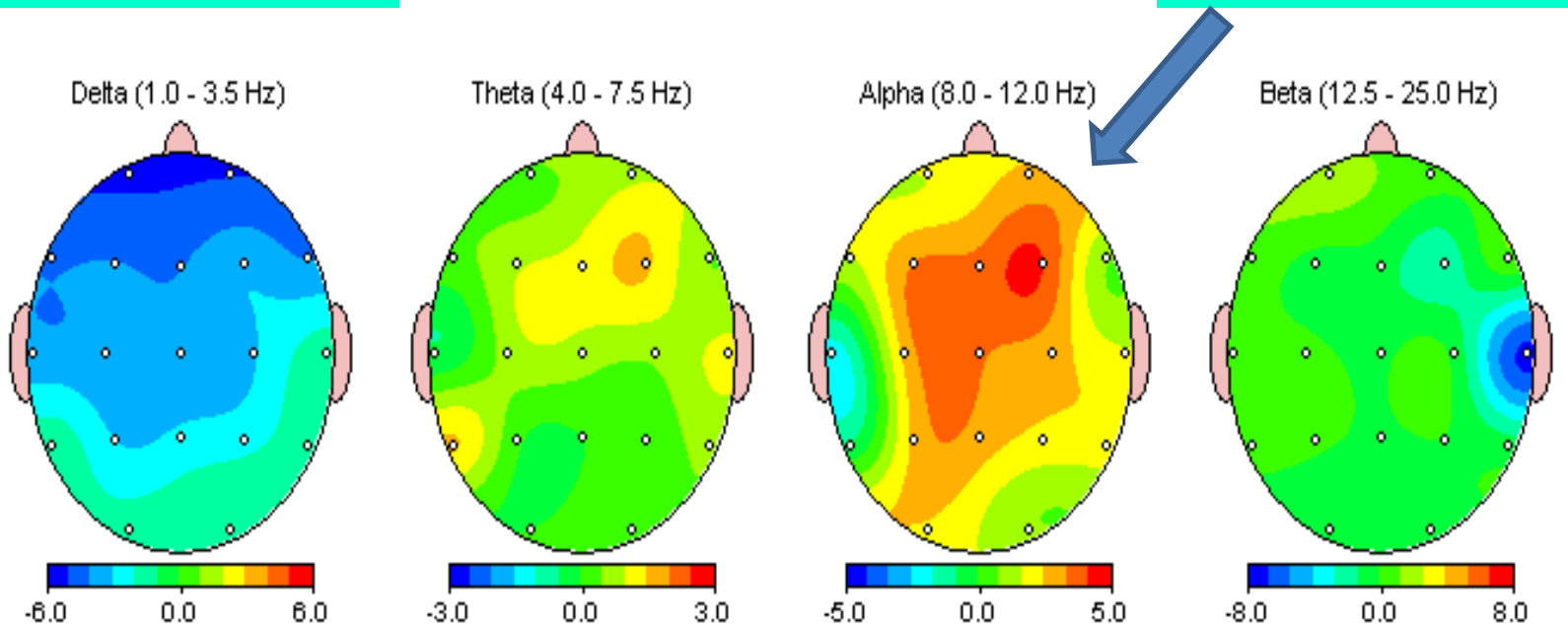
QEEG *Changes* in 30 Subjects Treated with 20 Minutes of CES

There is an increase in alpha activity with a simultaneous decrease in delta.

Blue = decrease Red = increase

Decrease Delta
More alert

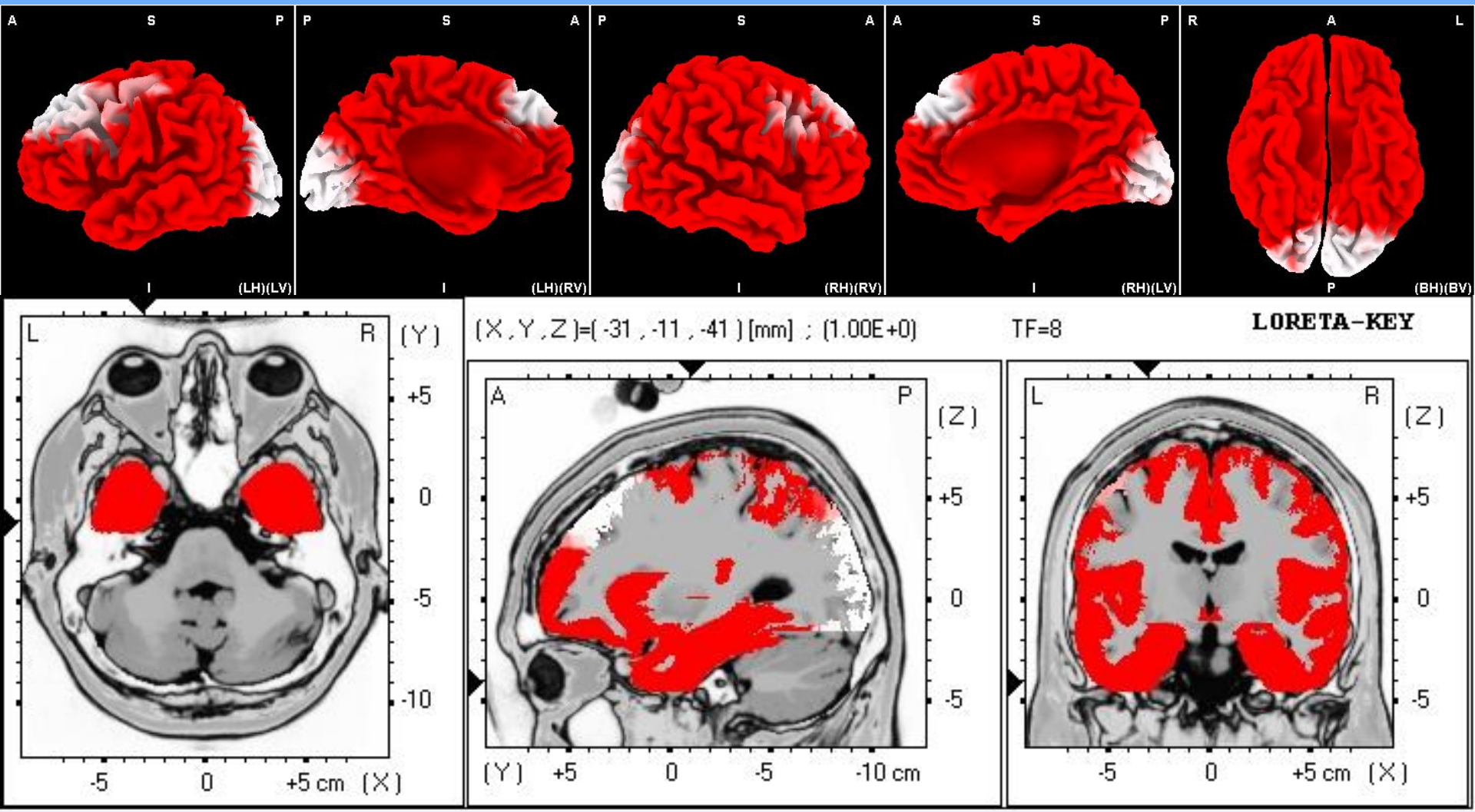
Increase Alpha
More relaxed



Kennerly, Richard. QEEG analysis of cranial electrotherapy: a pilot study.
Journal of Neurotherapy, (8)2, 2004.
Presented at the International Society for Neuronal Regulation conference, September 18-21, 2003, Houston, Texas

Low Resolution Tomography

Paired t-test for 8 Hz LORETA: Significant differences after 20 minutes of 0.5 Hz CES



Kennerly, Richard C. Changes in quantitative EEG and low resolution tomography following cranial electrotherapy stimulation. Ph.D. Dissertation, the University of North Texas. 529 pp., 81 tables, 233 figures, 171 references, 2006.

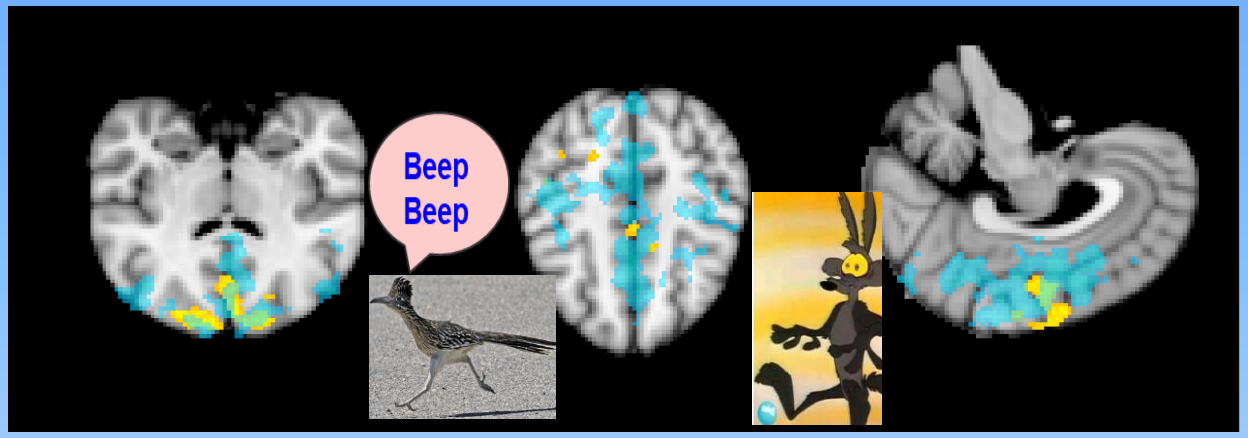
Effects of Cranial Electrotherapy Stimulation on fMRI Brain Activity in the Resting State

In anxiety subjects this shows cortical deactivation.

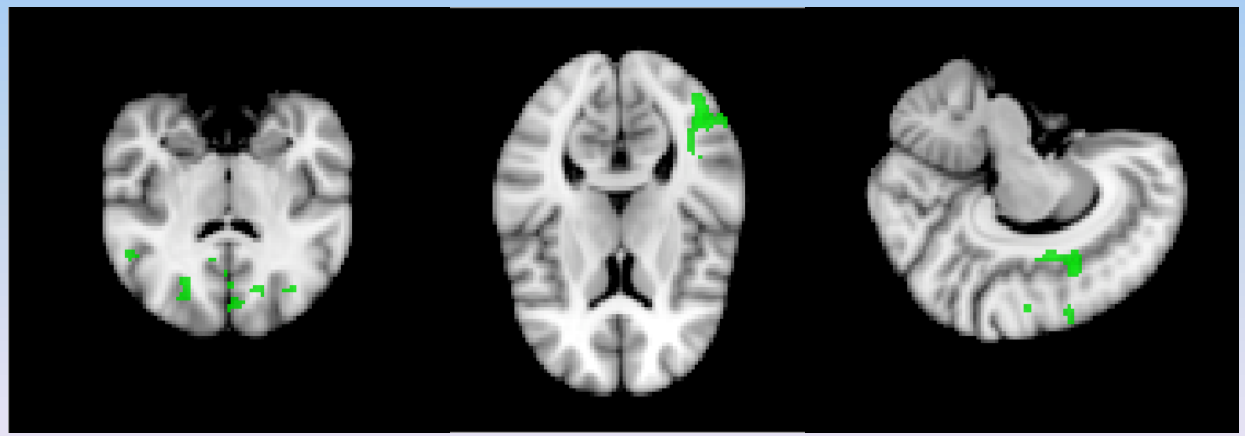
Basically we slow down an overactive **'Road-Runner'** brain.

Avoid treating the brain at 100 Hz

Regional deactivation associated with 0.5 Hz (blue) and 100 Hz (yellow)



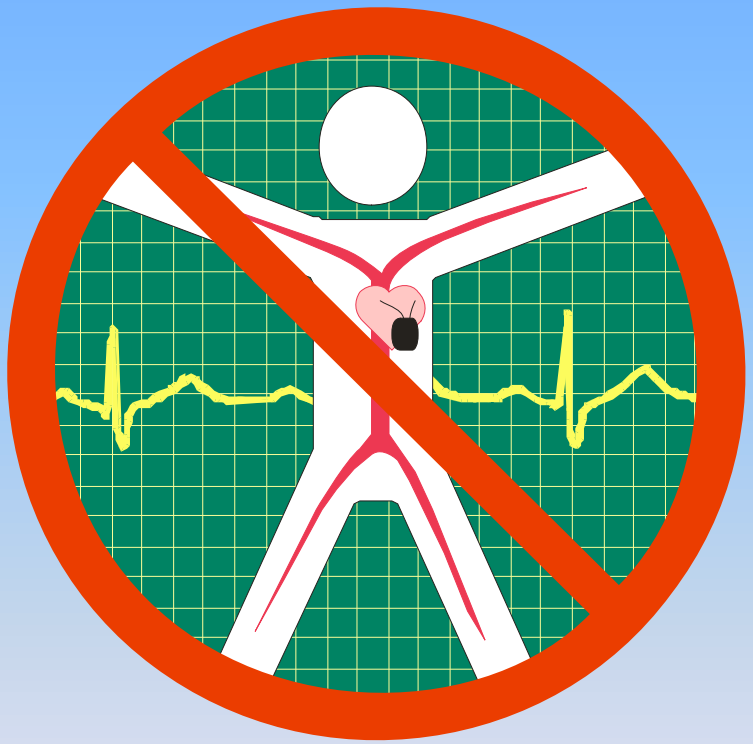
Regions positively associated with current intensity for 0.5 Hz



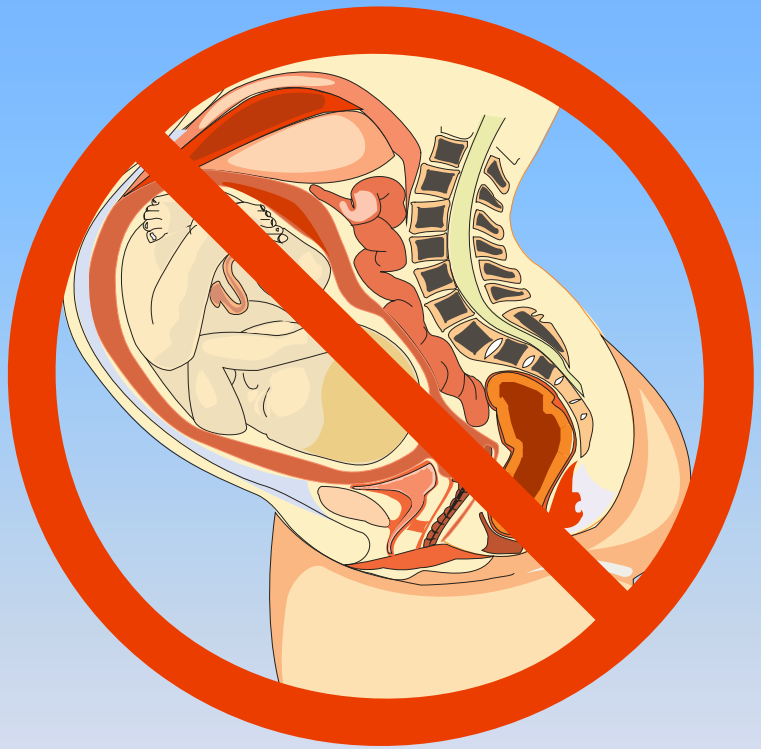
Feusner , Jamie D., Madsen , Sarah, Moody, Teena D., Bohon , Cara, Hembacher, Emily, Bookheimer , Susan Y. and Bystritsky, Alexander. Effects of cranial electrotherapy stimulation on **resting state brain activity**. *Brain and Behavior*. Pp 1-10, 2012.

Safety Considerations

Primary Contraindications



Interference with pre-1998 implants (*e.g.*, pacemakers and defibrillators) – No longer applicable?



Pregnancy – possible miscarriage and potential unsubstantiated legal arguments in case of developmental defects

Adverse Effects from CES

From 144 human studies encompassing 10,556 people where 8,792 received active CES:

9 headaches (0.10%, 1:977)

6 cases of skin irritation (0.07%, 1:1,465)

Are both mild and self-limiting.

If the current is set too high headaches, vertigo or nausea could develop and might endure for hours to days in people with a history of vertigo.

If the treatment is stopped too soon a heavy feeling accompanied by disorientation may persist for hours or even days.

Topics of Scientific Research on CES

Number of Pivotal Scientific Studies on Indicated Uses:

42 Anxiety

27 Insomnia

26 Depression

Research is done independently

Double blinding capabilities

Follow up studies show a durable effect

State (Situational) Anxiety

State anxiety can be effectively treated in a single CES treatment session. (Dental studies of CES)

This is demonstrated in medical and dental studies and in mechanistic studies of EEG and fMRI changes from a single CES treatment.

Results will vary based on initial anxiety level, length of treatment, comorbidities such as depression and overall patient health.

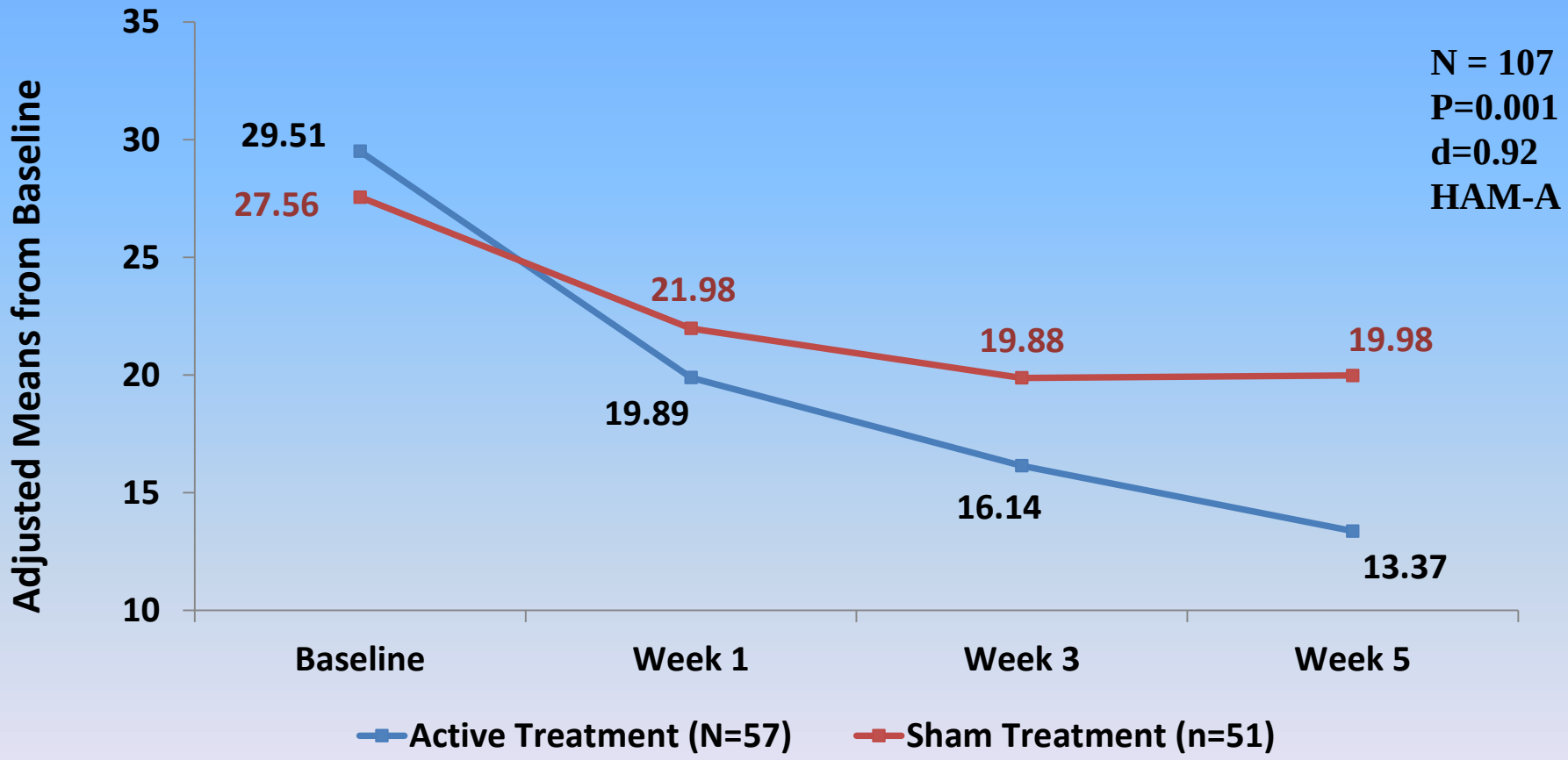
Trait (Chronic) Anxiety

May require up to 6 weeks of CES treatments to see significant reduction in trait anxiety levels.

Treatment outcome may also depend on comorbidities such as depression and insomnia.

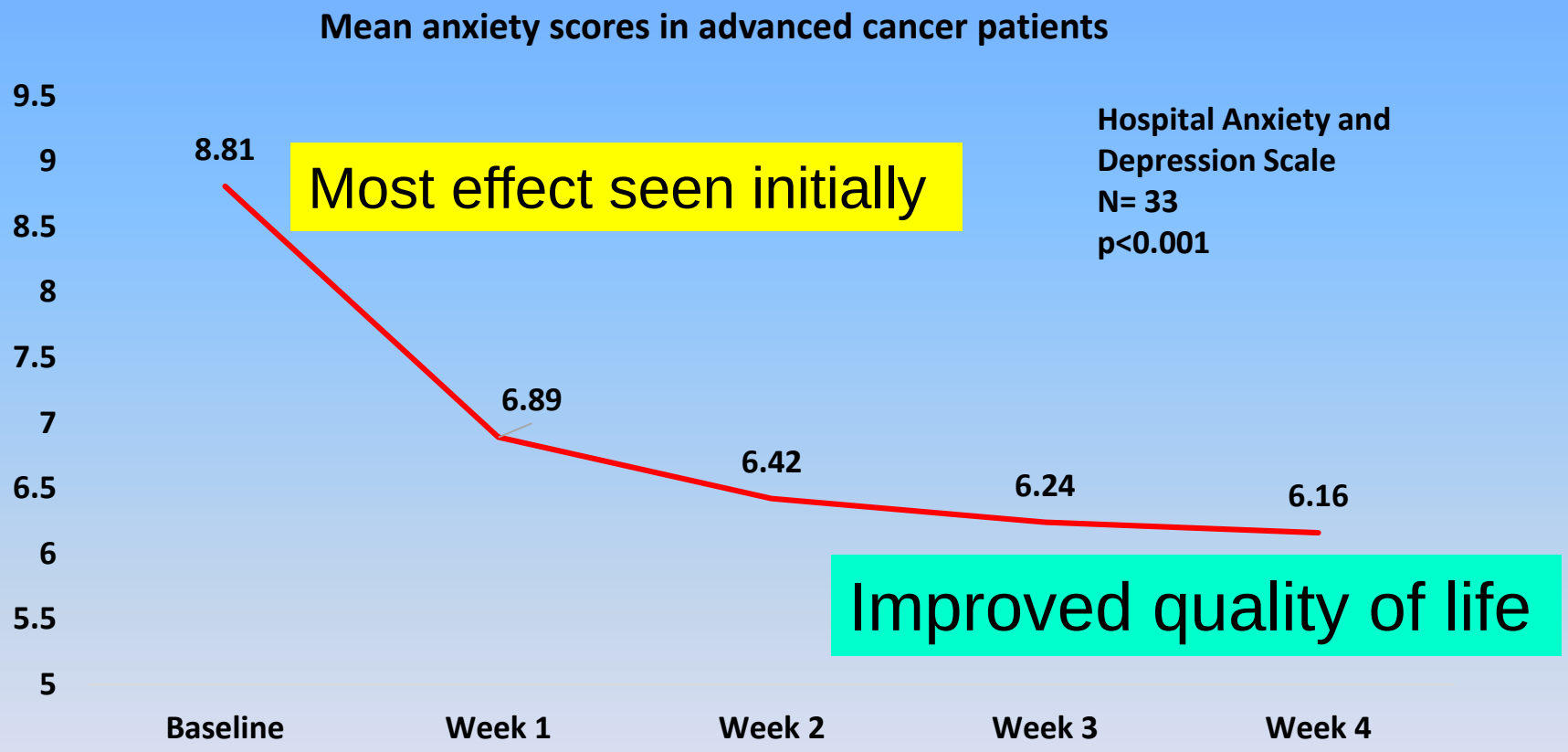
Mean Anxiety Scores

83.7% of the active group reported at least 50% improvement.
The active group reported 3 times more improvement than the sham group.



Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*. 2014; 164:171-177. Presented at the American Psychological Association National Conference, Honolulu, HI, July 2013.

Anxiety Improvement in Advanced Cancer Patients



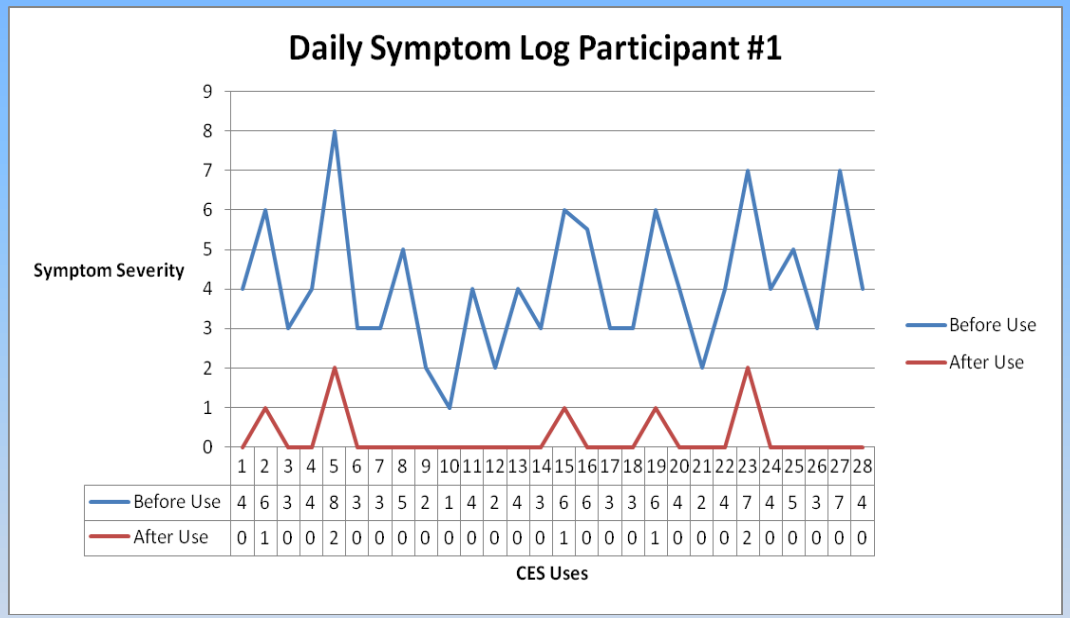
Cumulative response >>>>>>

Yennurajalingam S, Kang D-H, Hwu W-J, Padhye NS, Masino C, Dibaj SS, Liu DD, Williams JL, Lu Z, Bruera E. Cranial electrotherapy stimulation for the management of depression, anxiety, sleep disturbance, and pain in patients with advanced cancer: a preliminary study. *Journal of Pain and Symptom Management.* 2018; 55(2): 198-206.

Case Study PTSD in a 54 Year Old Male Veteran

Overall Decrease in Severity of 39% in One Month

PTSD Symptom Scale – Interview (PSS-I)	PRE	POST
PSS-I (Range: 0-51)	34	**13**
Re-experiencing (0-15)	7	**2**
Avoidance (0-21)	15	**7**
Increased Arousal (0-15)	12	**4**



Bracciano, Alfred G., Chang, Wen-Pin, Kokesh, Stephanie, Martinez, Abe, Meier , Melissa & Moore, Kathleen. Cranial Electrotherapy Stimulation in the Treatment of Posttraumatic Stress Disorder: A Pilot Study of Two Military Veterans. *Journal of Neurotherapy,* 16(1): 60-69, 2012.

Blue line how he felt before treatment and Red after Rx. All PTSD symptoms cut down by over 50%

NHS in the UK Finds Alpha-Stim Effective in GAD

Method

161 patients with **Generalized Anxiety Disorder**.

- They received 60 min per day Alpha-Stim CES for 6-12 weeks.
- Primary outcome was remission on the GAD-7 scale at 12 and 24 weeks.

Results

A very **significant decrease** in in **anxiety,** by using Alpha-Stim® CES.

- 72 (44.7%) achieved remission on the GAD-7 at 12 weeks
- 77 (47.8%) achieved remission on the GAD-7 at 24 weeks

Morriss R, Xydopoulos G, Craven M, Price L, Fordham R. Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalised anxiety disorder. J Affect Disord. 2019 Jun 15;253:426-437.

Alpha-Stim Provides a Cost Savings

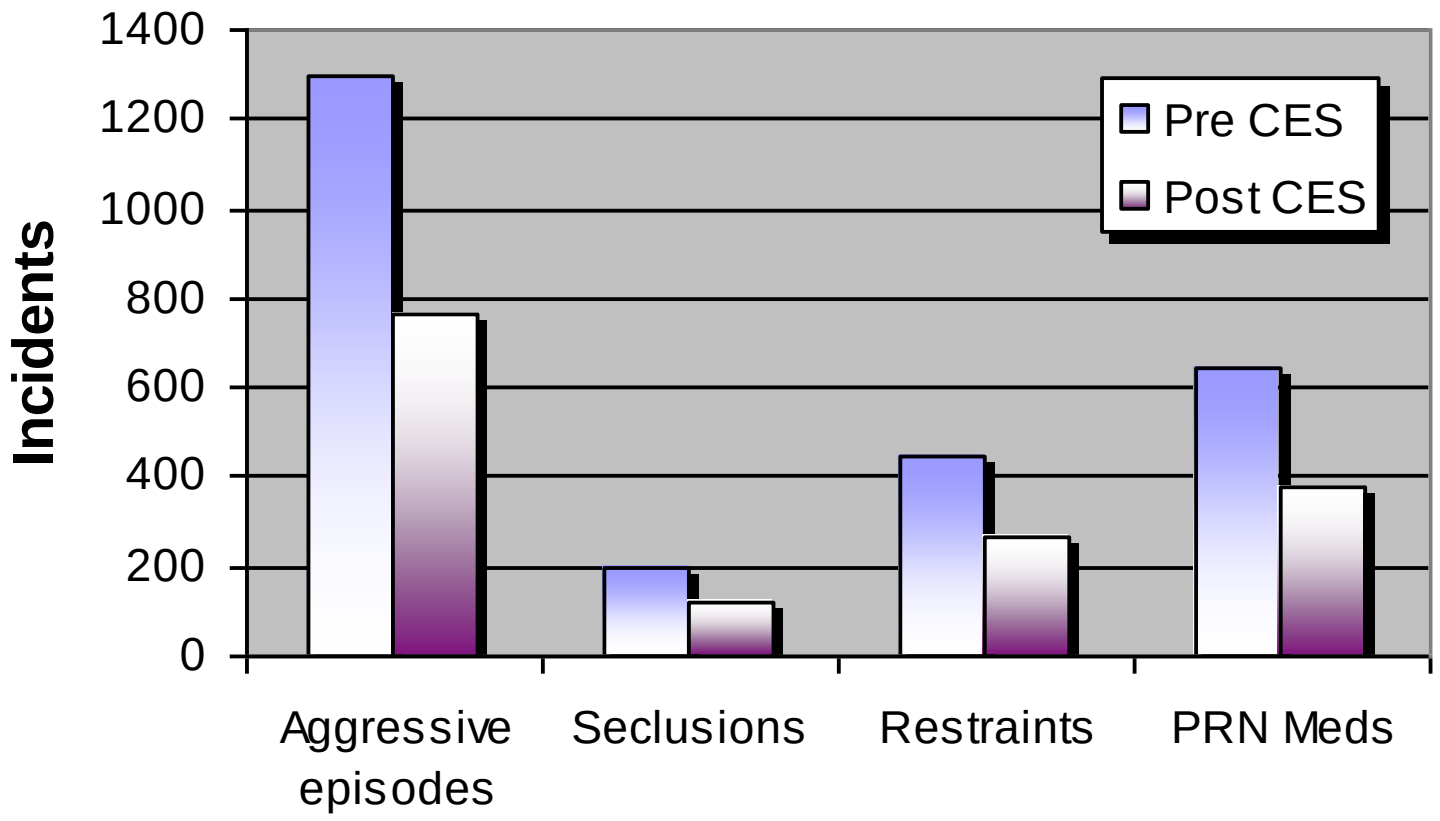
The current study demonstrated clinical and cost effectiveness of Alpha-Stim CES in people with generalized anxiety disorder (GAD) who had not responded to low intensity psychological treatment in a routine health service.

Cost savings = £540.88 per patient

In USD = $652.226

Morriss R, Xydopoulos G, Craven M, Price L, Fordham R. Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalised anxiety disorder. J Affect Disord. 2019 Jun 15;253:426-437.

3 Month Trial with 48 Severe Aggressive Patients



Locked facility in Texas

With CES every category reduced by ~ 40%

41% reduction in episodes of violence (P<.001)
40% reduction in episodes requiring seclusion (P<.05)
40% reduction in episodes requiring restraint (P<.001)
and 42% fewer as-needed emergency medications (P<.01).
The decrease of 271 PRN med doses in 3 months saved >$12,000 for these med expenses alone.

Childs, Allen and Price, Larry. Cranial electrotherapy stimulation reduces aggression in violent neuropsychiatric patients. *Primary Psychiatry*, 14(3):50-56, 2007; Presented at American Psychiatric Association annual meeting, 2007.

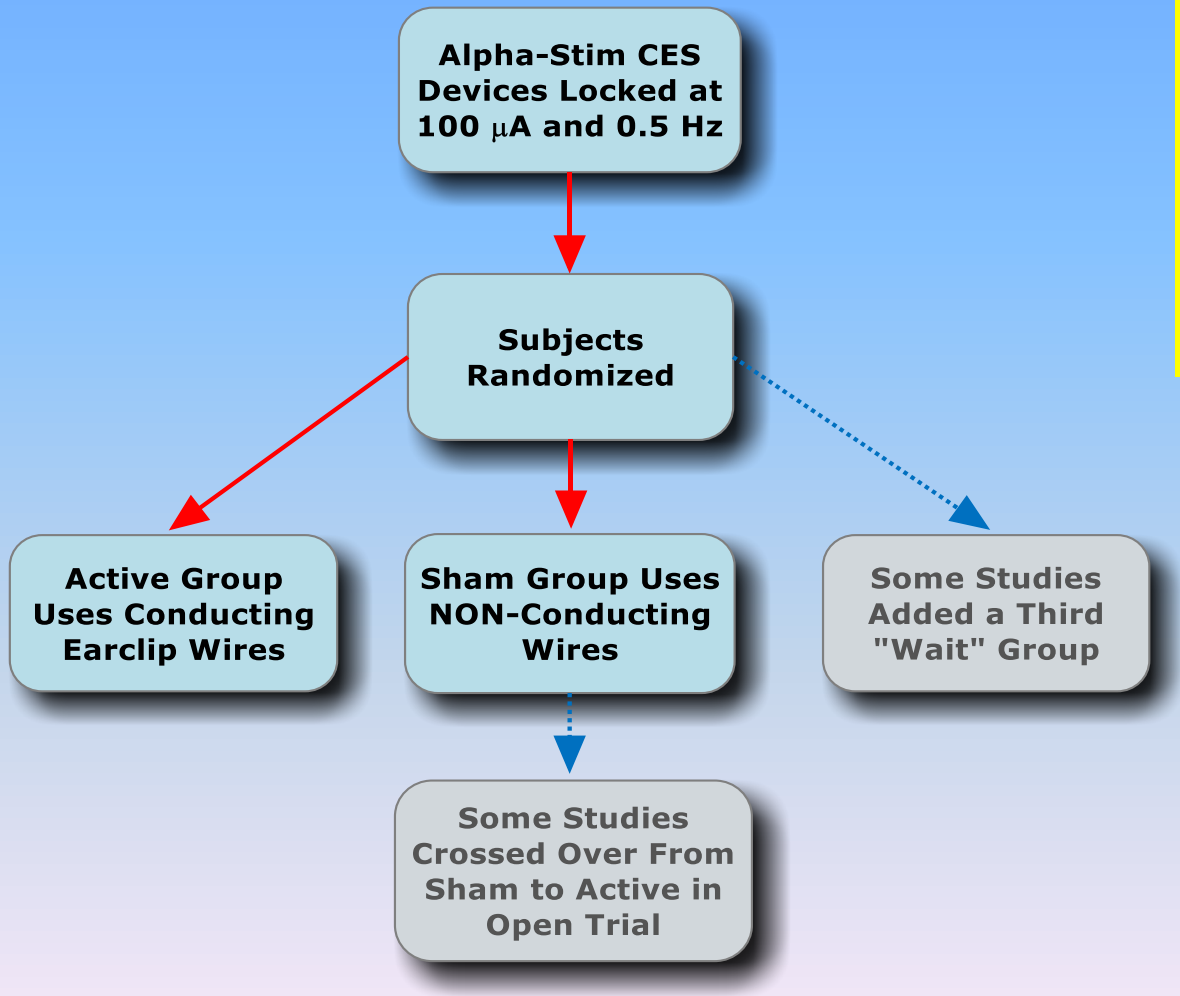
Insomnia

Insomnia patients usually see results after one treatment.

Or it may take up to 4 weeks of treatment, especially if insomnia is associated with depression.

Recent study completed at Walter Reed showed an average increase of +43 minutes of sleep after only 5 treatments.

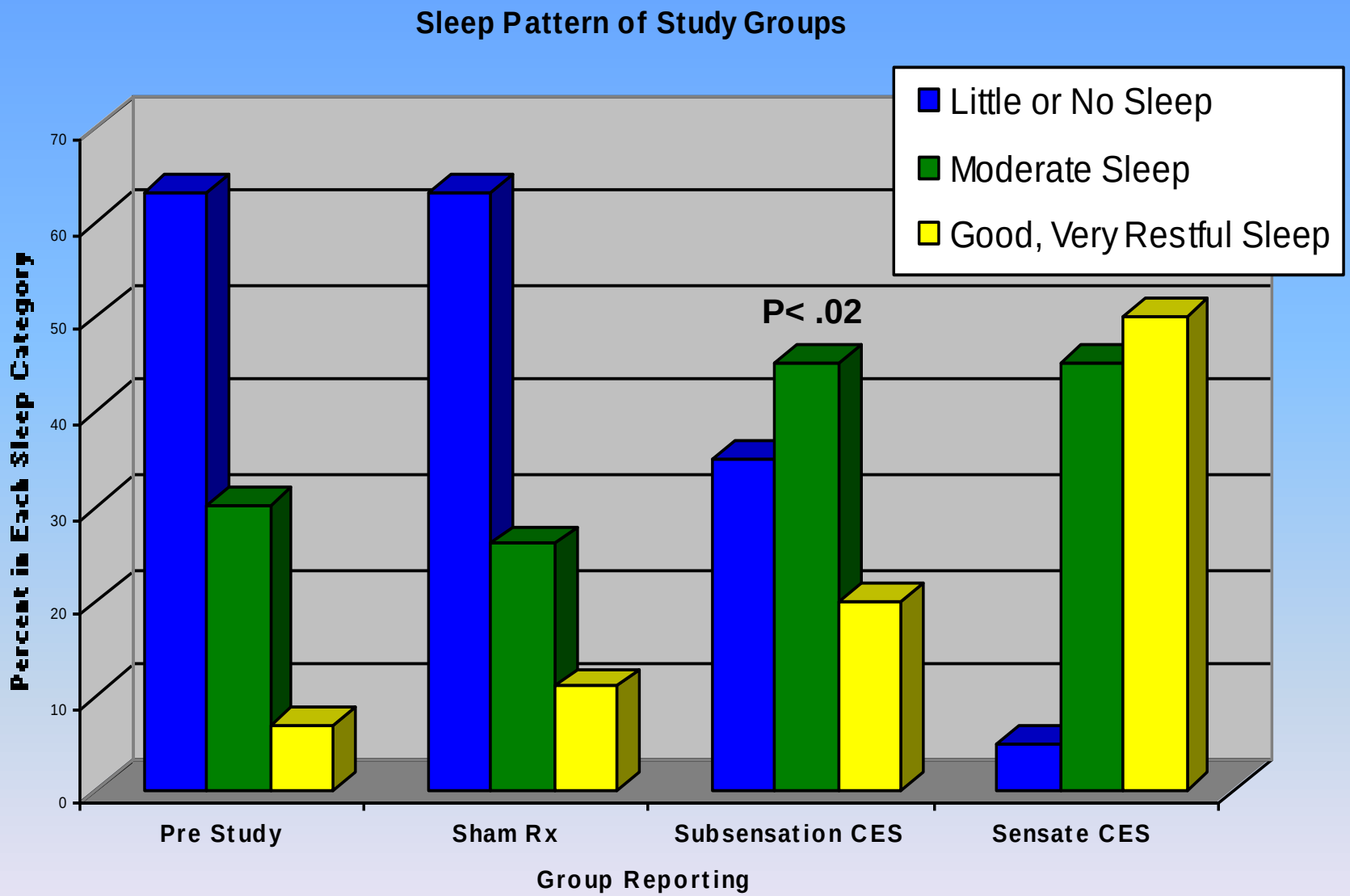
Protocol Used in All Alpha-Stim® CES RCT Double Blind Studies



Real life effects are better than studies since we turn down the current

Remember dosage is important. Less current means longer treatment times

3 Week RCT of CES for Insomnia in Fibromyalgia Patients

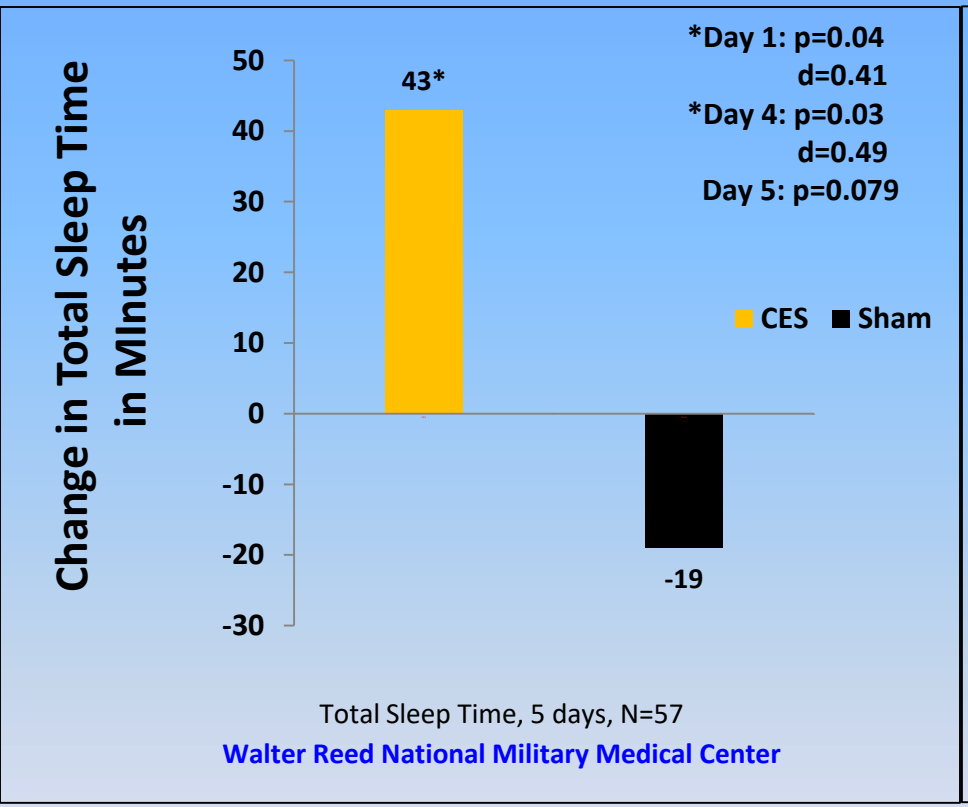


Lichtbroun, A.S., Raicer, M.M.C. and Smith, R.B. The treatment of fibromyalgia with cranial electrotherapy stimulation. *Journal of Clinical Rheumatology*. 7(2):72-78, 2001.

Presented at the 15th Annual International Symposium on Acupuncture and Electro Therapeutics, Columbia University, New York, October 1999.

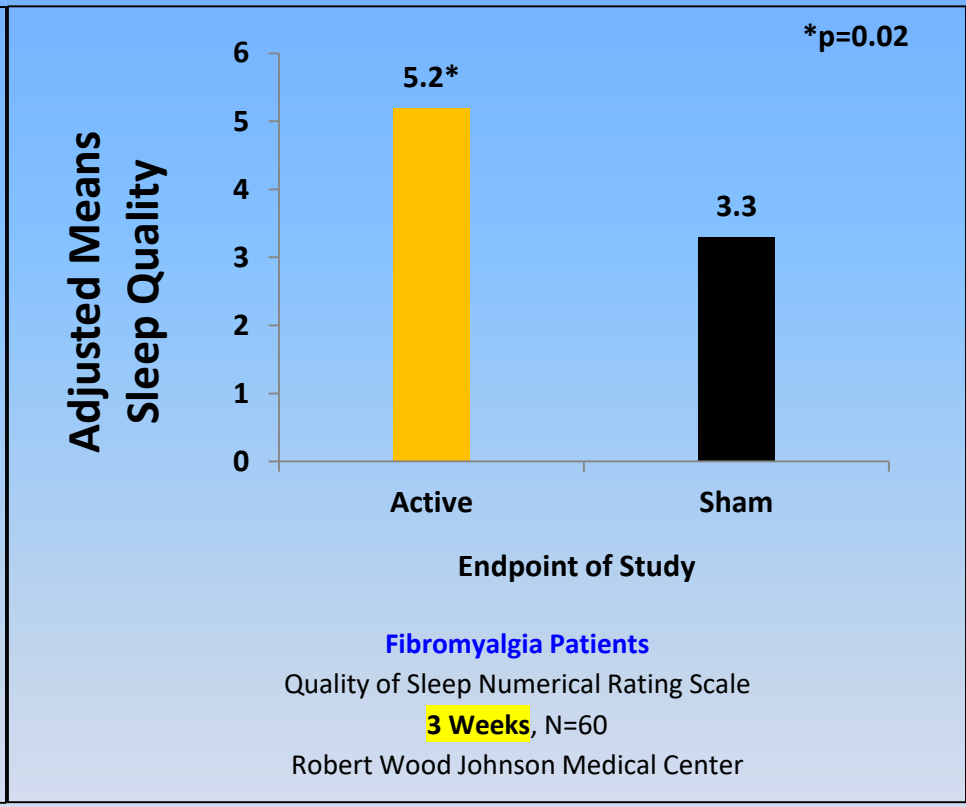
Insomnia

5 day sleep study @ Walter Reed military hospital - 43 more minutes of average sleep/night



Total Sleep Time, 5 days, N=57

Walter Reed National Military Medical Center



Fibromyalgia Patients

Quality of Sleep Numerical Rating Scale

3 Weeks, N=60

Robert Wood Johnson Medical Center

Lande, R. Gregory and Gragnani, Cynthia. Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study. *Complementary Therapies in Medicine,* 21(1):8-13, 2013.

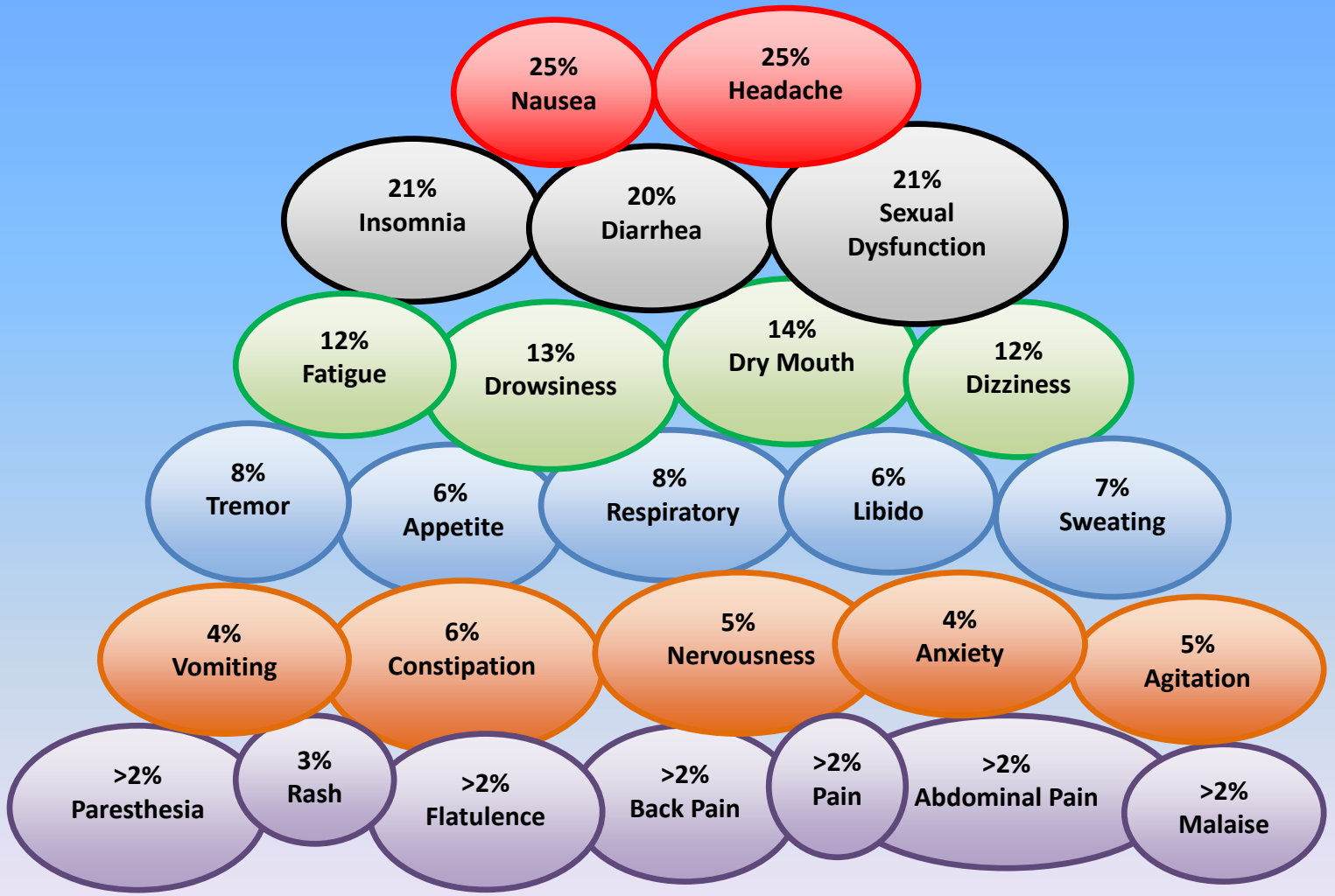
Lichtbroun, Alan S., Raicer, Mei-Ming C., and Smith, Ray B. The treatment of fibromyalgia with cranial electrotherapy stimulation. *Journal of Clinical Rheumatology,* 7(2):72-78, 2001.

Depression - Goal

Expect a **minimum of 3 weeks** of **daily CES treatment** before significant results are seen and the patient can use CES on a reduced schedule. Be as consistent as possible.

A patient who suffers from anxiety with a depression component will take up to 3 weeks to improve as well.

Example of Side Effect Profile for the Popular Antidepressant Zoloft (sertaline)

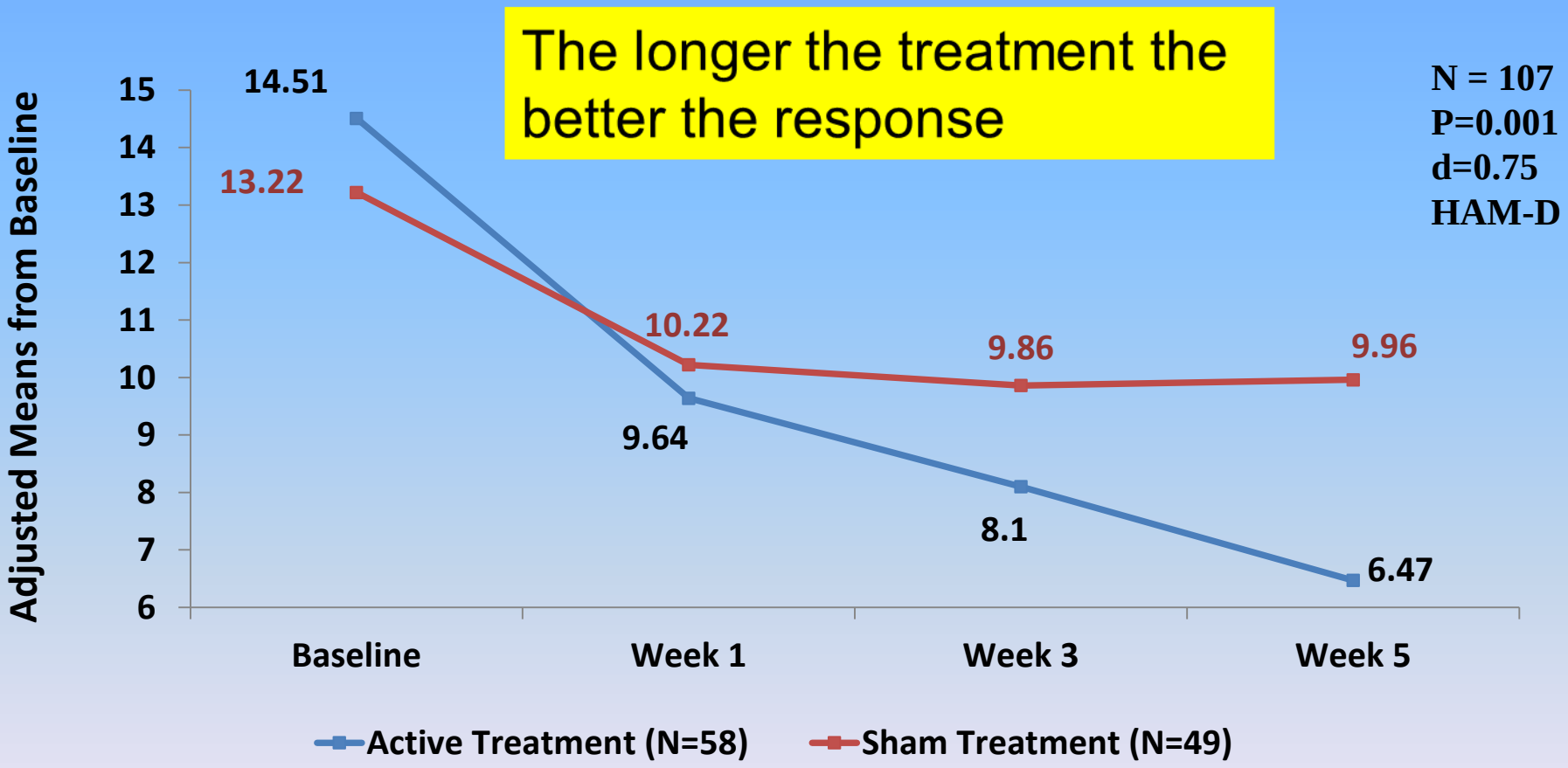


Results from a placebo controlled clinical trial (n=2799)

As cited by www.drugs.com/sfx/sertraline-side-effects.htm

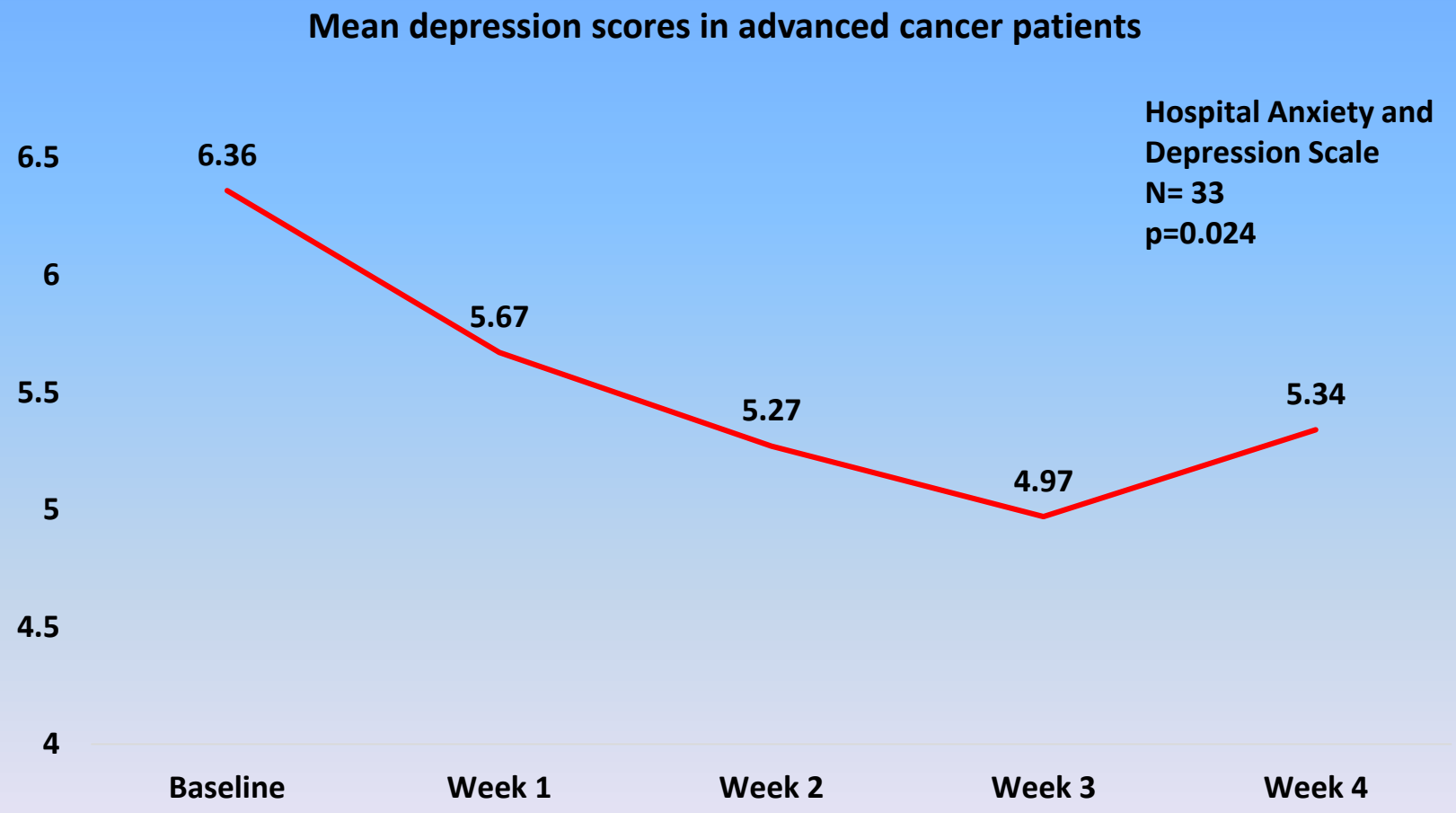
Mean Depression Scores

82.2% of the active group reported at least 50% improvement.
The active group reported 12 times more improvement than the sham group.



Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*. 2014; 164:171-177. Presented at the American Psychological Association National Conference, Honolulu, HI, July 2013.

Depression Improvement in Advanced Cancer Patients



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Pain Management

- Acute
- Chronic
- Post-operative

Usually results are seen from the first treatment.

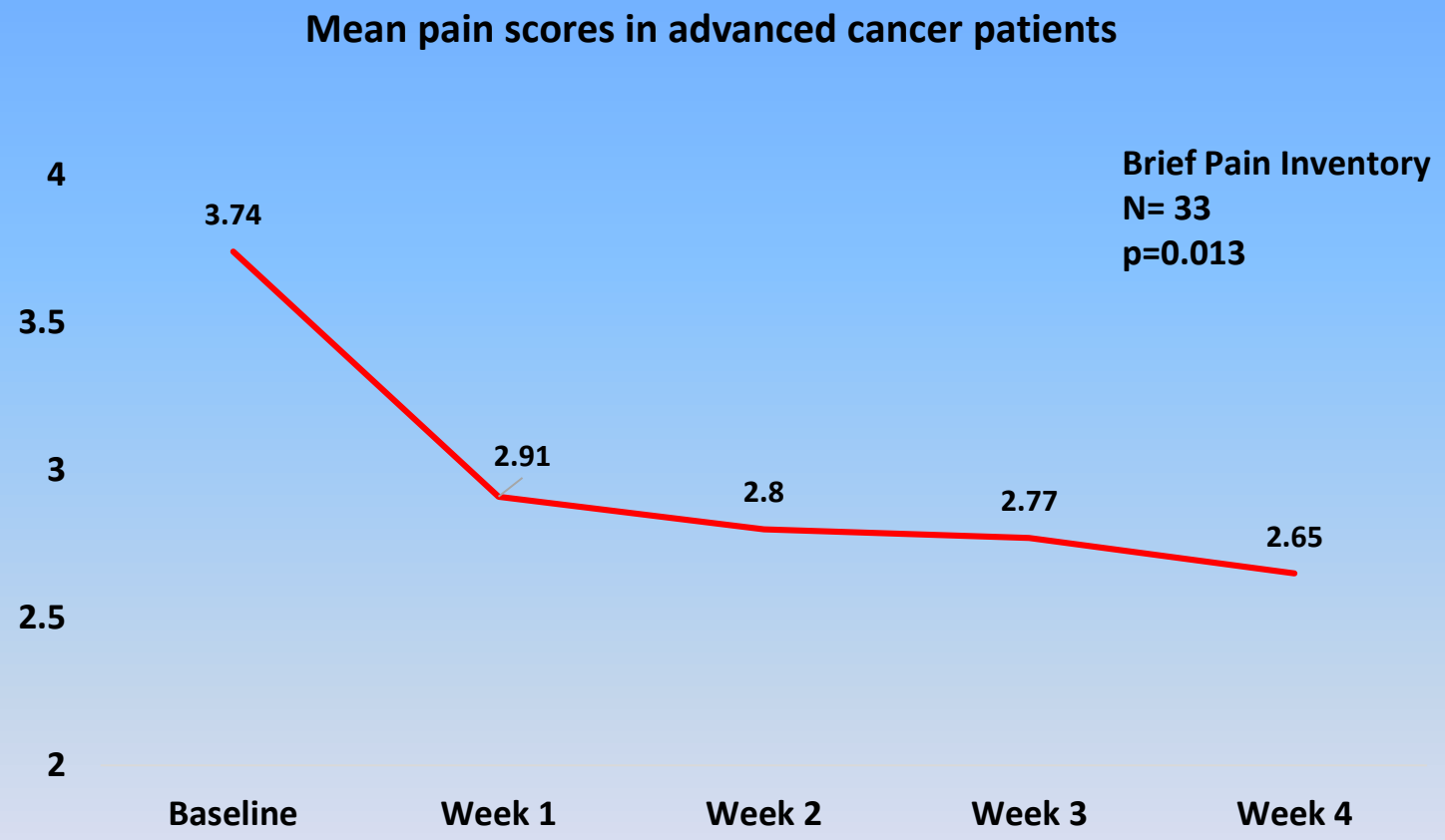
There is no risk of accommodation or addiction.

Pain relief is cumulative with continued use.

What is the first thing you think of when your computer breaks?

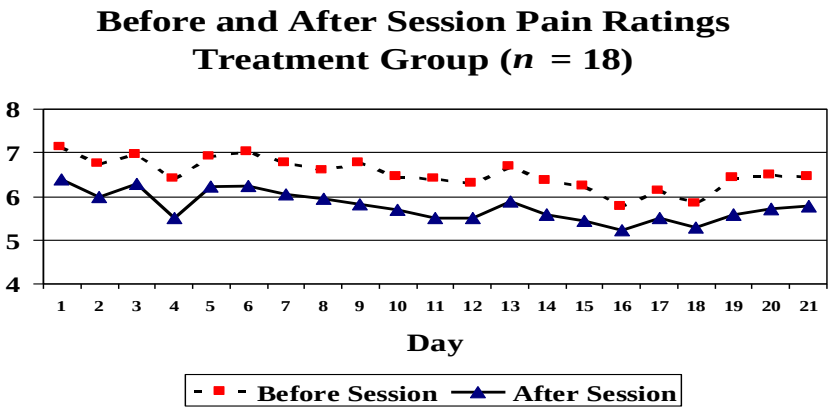
What is the first thing you think of treating when you have pain?

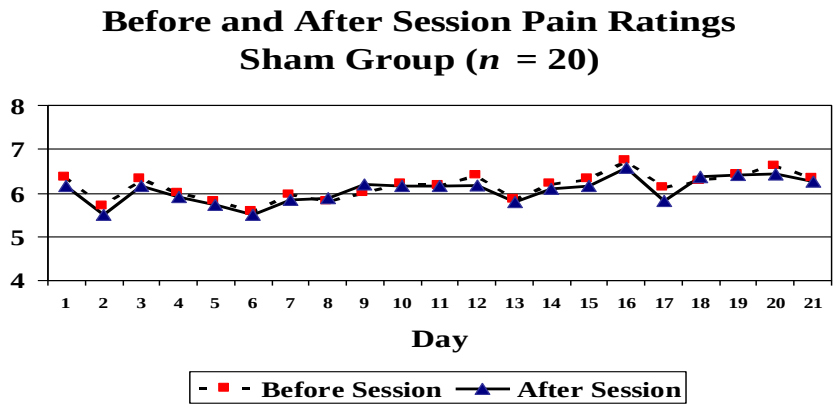
Pain Reduction in Advanced Cancer Patients

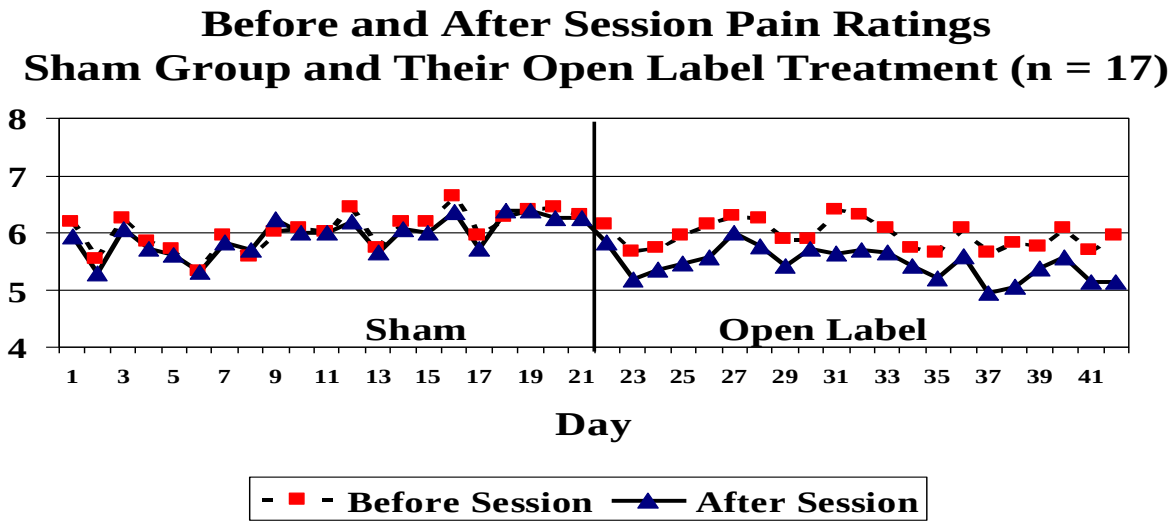


Yennurajalingam S, Kang D-H, Hwu W-J, Padhye NS, Masino C, Dibaj SS, Liu DD, Williams JL, Lu Z, Bruera E. Cranial electrotherapy stimulation for the management of depression, anxiety, sleep disturbance, and pain in patients with advanced cancer: a preliminary study. *Journal of Pain and Symptom Management.* E-published ahead of print, September, 2017.

VA Houston CES Spinal Cord Injury Study



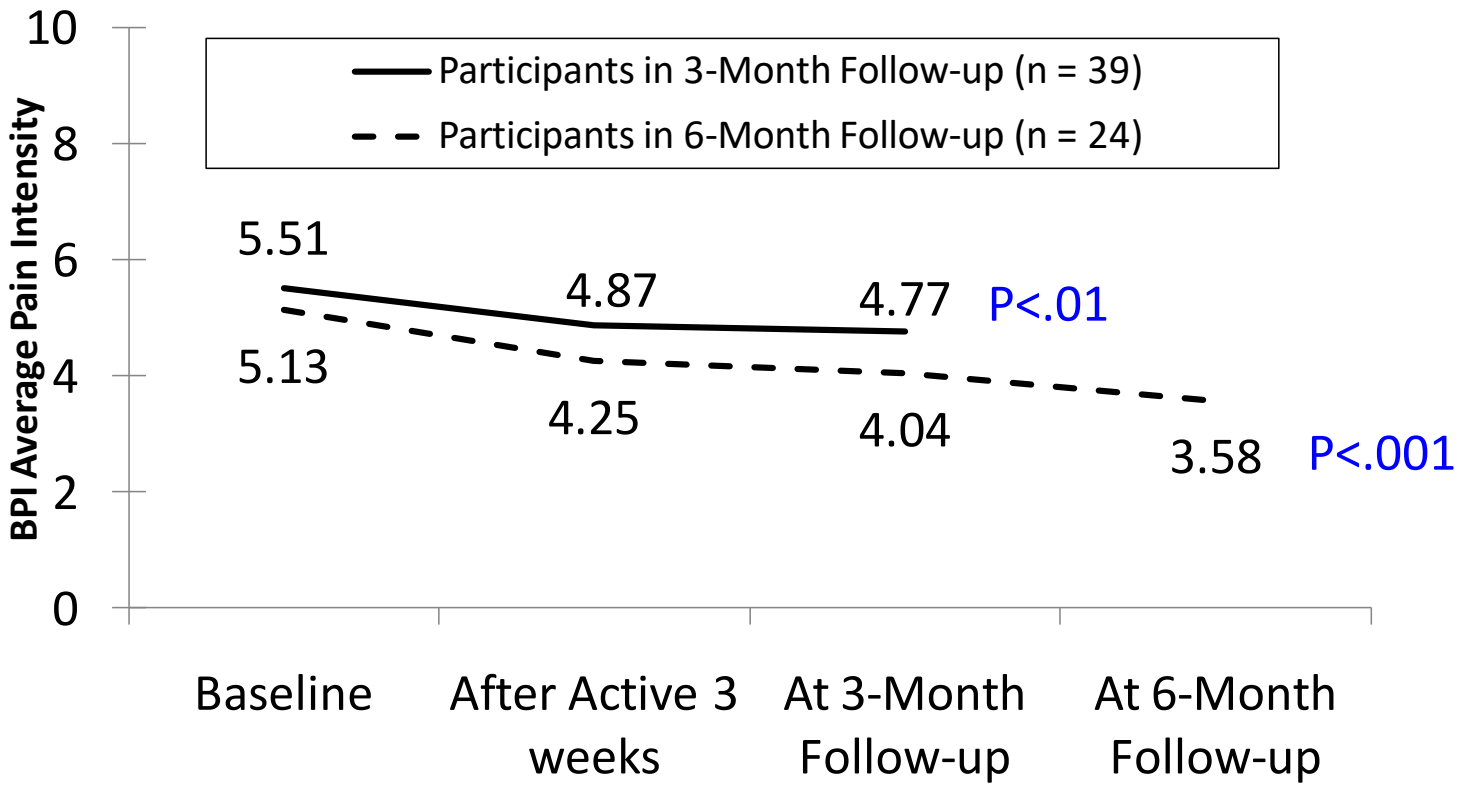




Figures 1, 2, and 3: Daily Pain Rating for Active CES and Sham CES Groups

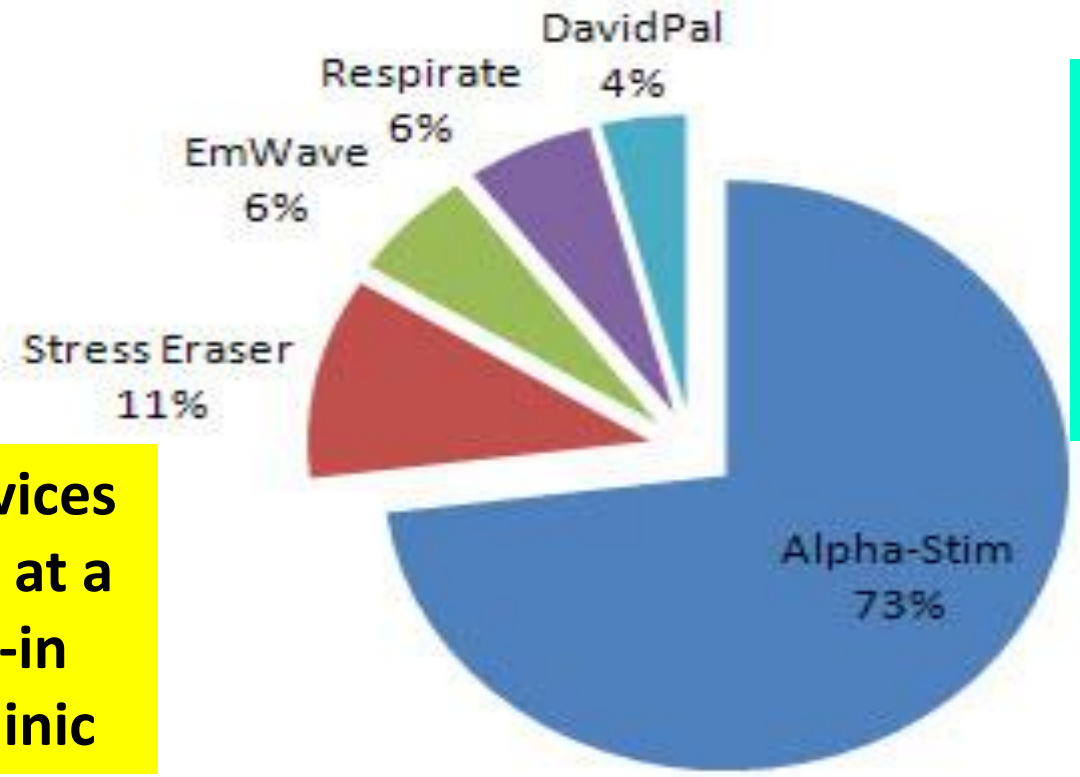
Tan, Gabriel, Rintala, Diana H., Thornby, John, Yang, June, Wade, Walter, and Vasilev, Christine. Using cranial electrotherapy stimulation to treat pain associated with spinal cord injury. *Journal of Rehabilitation Research and Development*, 43(4):461-474, 2006.

3 Year, 5-Site Spinal Cord Injury Study



Tan, Gabriel, Rintala, Diana, Jensen, Mark P., Richards, J. Scott, Holmes, Sally Ann, Parachuri, Rama, Lashgari-Saegh, Shamsi and Price, Larry R. Efficacy of cranial electrotherapy stimulation for neuropathic pain following spinal cord injury: a multi-site randomized controlled trial with a secondary 6-month open-label phase.
The Journal of Spinal Cord Medicine, 34(3):285-296, 2011

CAM Devices Chosen by 32 Veterans Across 197 Group Visits

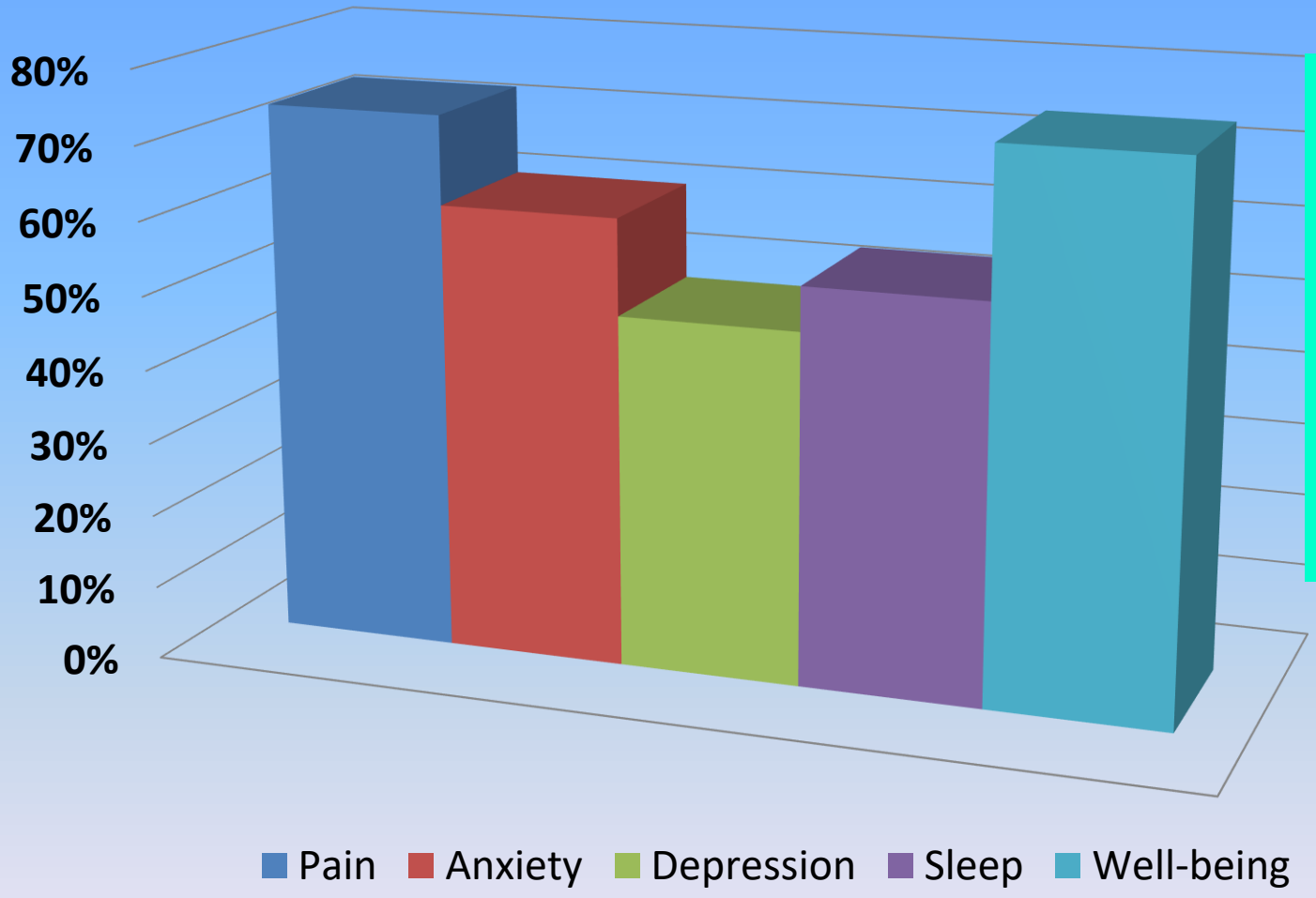


Which device did they pick 73% of the time?

5 devices used at a walk-in VA clinic

Tan, Gabriel, Dao, Tam K., Smith, Donna L., Robinson, Andrew and Jensen, Mark P. Incorporating Complementary and Alternative Medicine (CAM) Therapies to Expand Psychological Services to Veterans Suffering From Chronic Pain. *Psychological Services*, 7(3):148–161, 2010.

Improvement in 32 Veterans After an Average of 5 Treatments (158 Total Treatments)

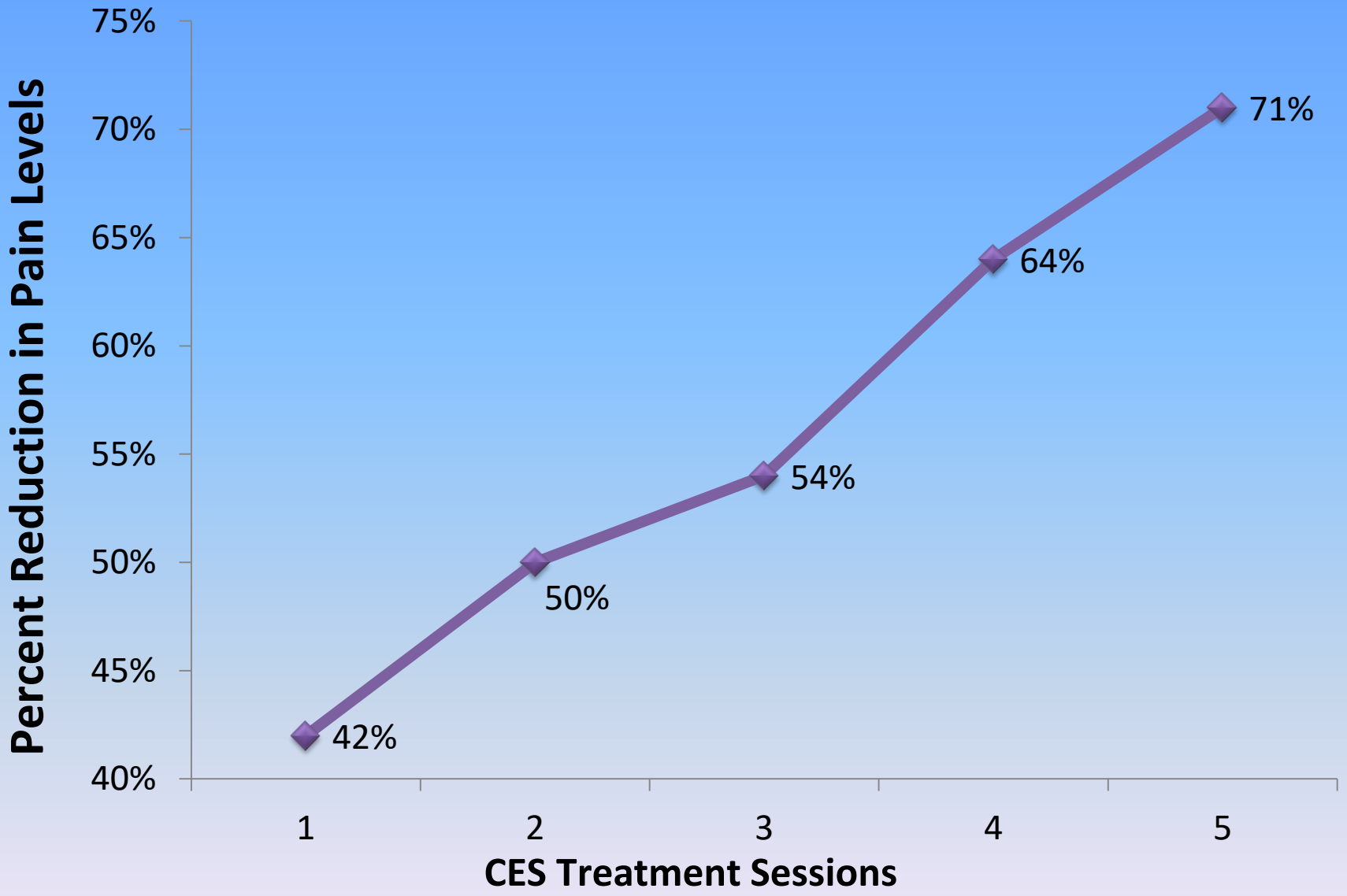


People report they feel better very fast and before we see changes in psychological measurements

Alert & Relaxed

Tan, Gabriel, Dao, Tam K., Smith, Donna L., Robinson, Andrew and Jensen, Mark P. Incorporating Complementary and Alternative Medicine (CAM) Therapies to Expand Psychological Services to Veterans Suffering From Chronic Pain. Psychological Services, 7(3):148–161, 2010.

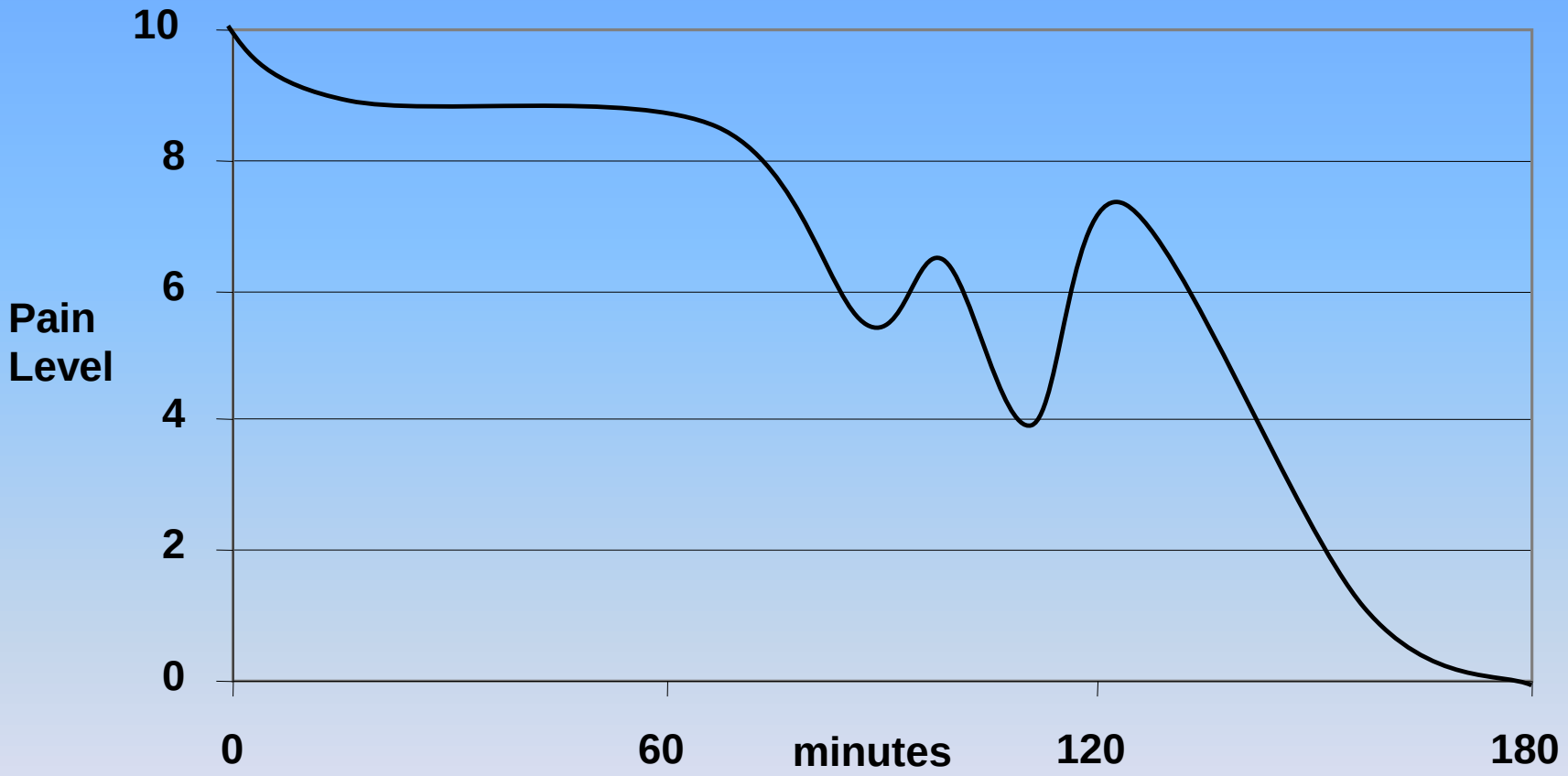
Cumulative Improvement in Pain After 1-5 CES



Holubec, Jerry T. Cumulative Response from Cranial Electrotherapy Stimulation (CES) for Chronic Pain. *Practical Pain Management*, 9(9):80-83, 2009.

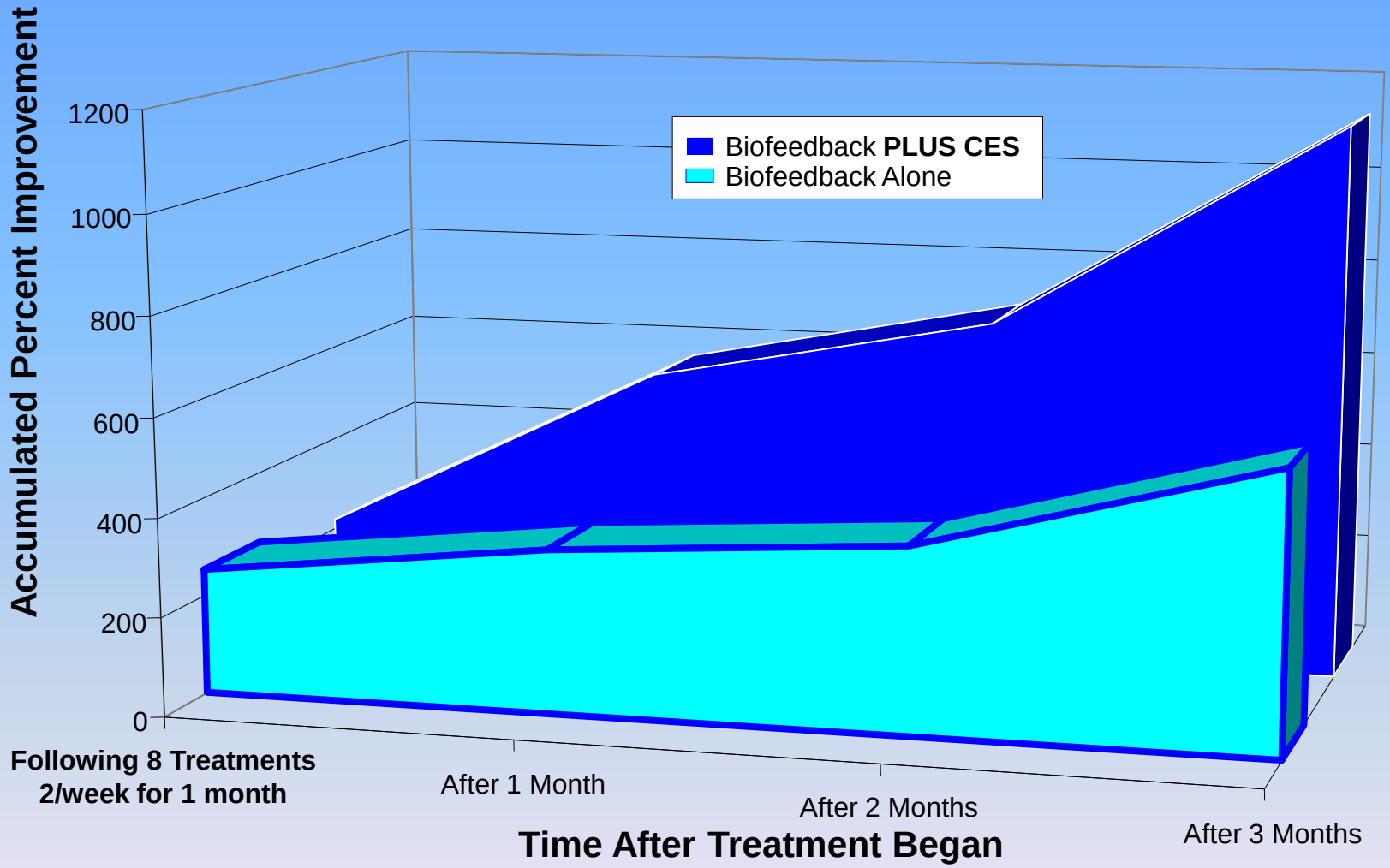
Example of the CES Response Over Time in a Patient with Severe Migraine

Courtesy of COL Michael Singer, Walter Reed Army Medical Center



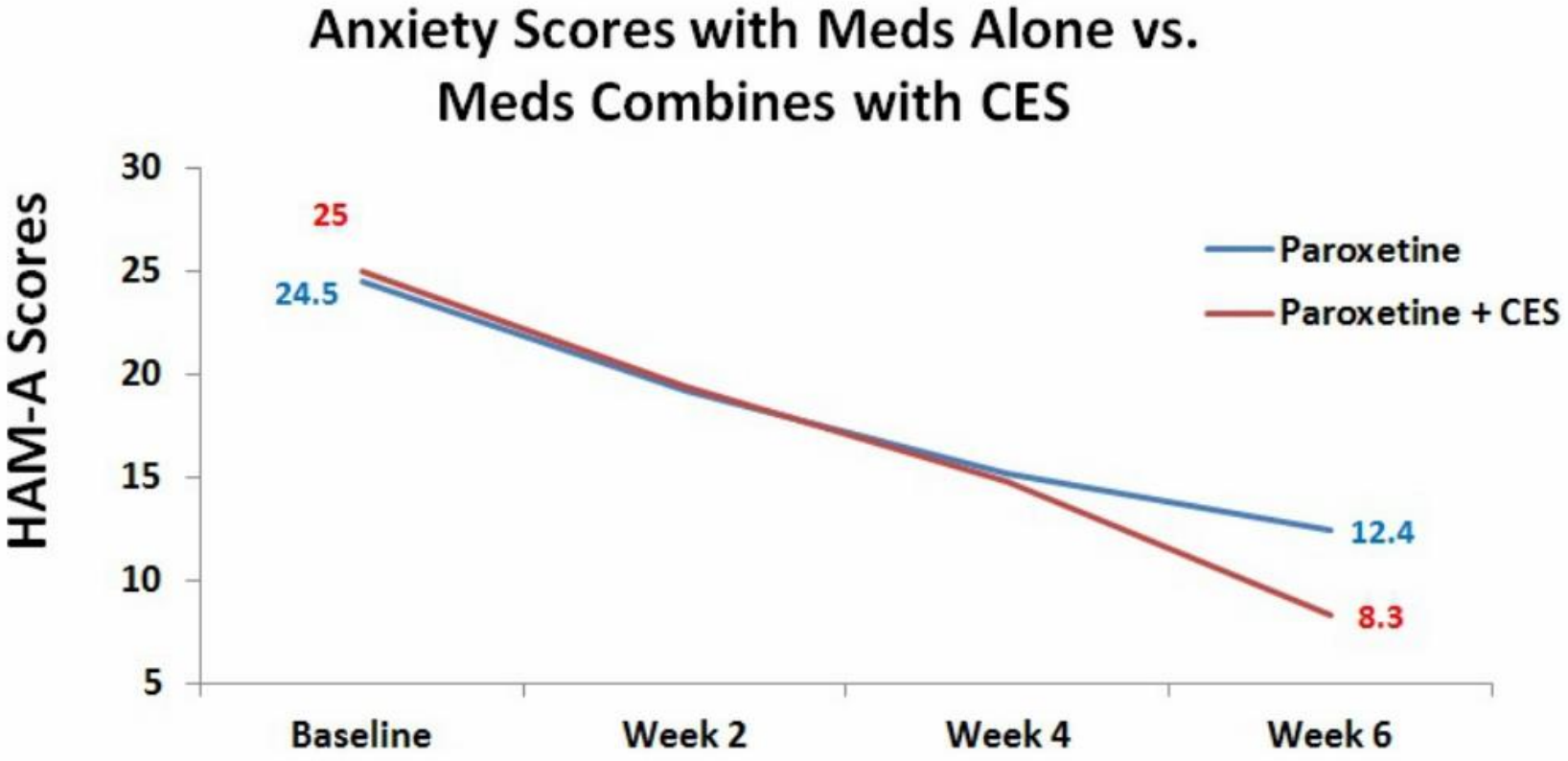
Stay with it!

Migraine Headaches -- Frequency and Intensity
CES Doubles Effects of Biofeedback



Brotman, Philip. Low-intensity transcranial electrostimulation improves the efficacy of thermal biofeedback and quieting reflex training in the treatment of classical migraine headache. *American Journal of Electromedicine,* 6(5):120-123, 1989. Doctoral dissertation, City University Los Angeles, 117 pages, 1986.

Alpha-Stim with Medication



The treatment group had signficant reduction in anxiety (51%, P<0.05) over 6 weeks but the CES + med group did significantly better than medication alone (67%, P<0.01).

LU Ling, HU Jun. A comparative study of anxiety disorders treatment with Paroxetine in combination with cranial

Summary

- **CES is safe**
- **CES is easy to use**
- **CES is proven effective**
- **CES works quickly and lasts**
- **CES is FDA, CE and ISO certified**
- **DoD/VA is using and researching CES**
- **CES is available to help you NOW!**

Practical Protocols

For peripheral pain treatment with microcurrent electrical therapy (MET)…

General Indications

- ✓ All headaches, including migraine
- ✓ Any nerve, muscle, and articular pain
- ✓ Sprains, strains, and spasms
- ✓ Paresis
- ✓ Post-operative pain and scars
- ✓ Trigger and Acupuncture points
- ✓ Decubitus ulcers and fractures

  (>1 hour/day at 0.5 Hz and 100 μA)

First, Analyze The Pain

- ✓ Diagnosis is helpful, but not everything
- ✓ Where are all pain/problems located?
- ✓ What position(s) exacerbate them?
- ✓ How bad are they on a 0 - 10 scale right now?
- ✓ Note any obvious signs
- ✓ Note any special symptoms
- ✓ Think holistically, note any related problems
- ✓ Note all scars and old injuries

Second, Prepare Device

- ✓ **Attach probes to Alpha-Stim**
- ✓ **Place electrodes on probes**
- ✓ **Wet each electrode with Alpha Conducting Solution**
- ✓ **Set frequency to 0.5 Hz**
- ✓ **Use 100 Hz *only* for initial treatment of inflammatory joint disease in remission**
  (*i.e.*, "dry joint"
  (10 - 20 seconds per site)
- ✓ **Set current to maximum of 600 microamperes, or to a comfortable level on the head**
- ✓ **Set timer for probe**

Basic 5-Step Protocol

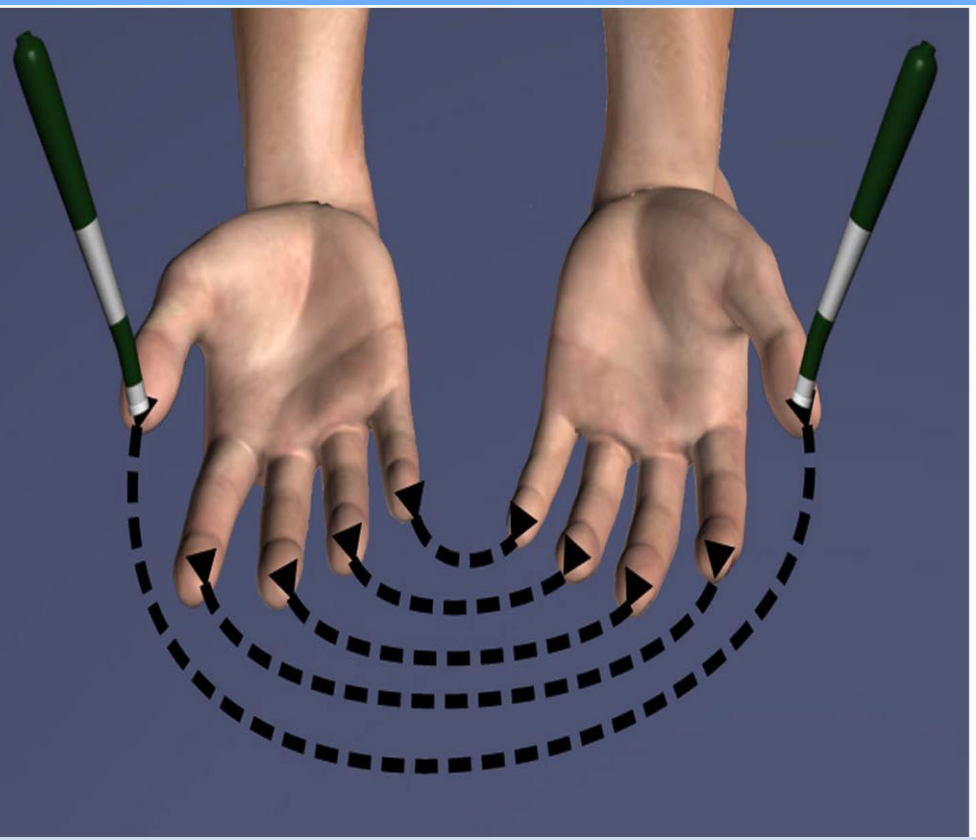
1. First treat in a big "**X**" beyond the area(s) of pain
2. Then treat through the areas in three dimensions, like a star (*e.g.,* 2 obliques, A-P, M-L)
3. Treat the opposite side even if it is asymptomatic
4. Always connect both sides (*most important step*)

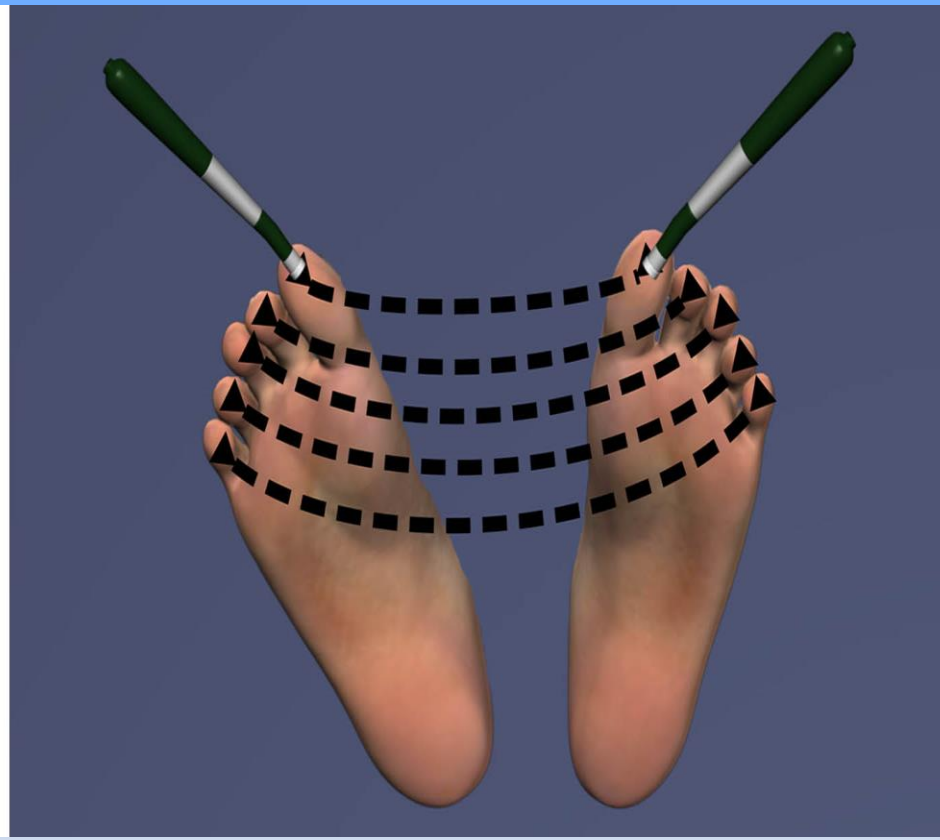
✓ Press fairly hard

✓ Reevaluate pain about every 1 - 2 minutes ("set")

5. Finish with CES

The 1-Minute Protocol

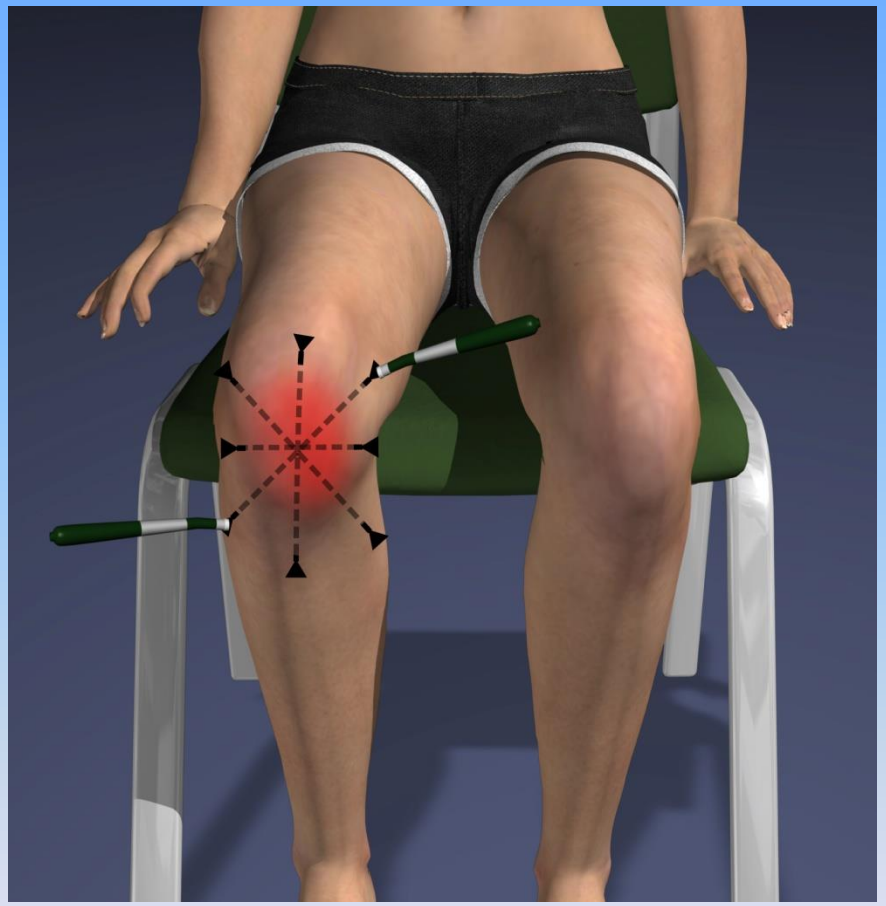




1. This treats the entire UE, neck and shoulders

2. This treats the entire LE, pelvis and low back

Example 1: L.E. Pain (knee)

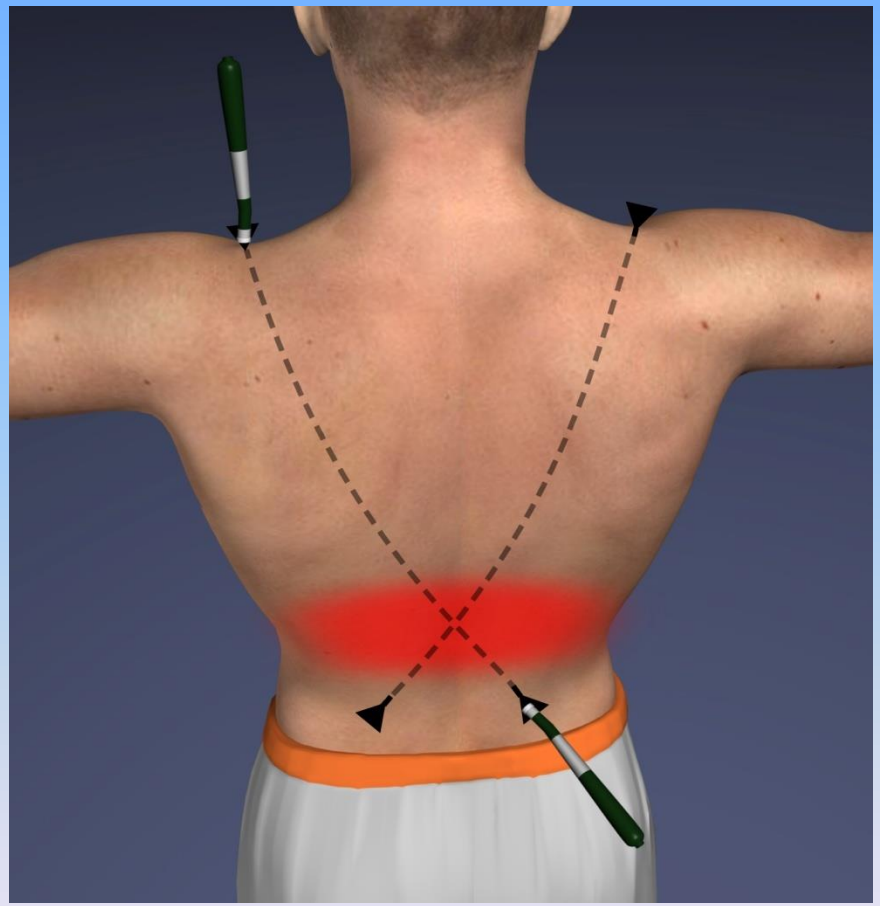


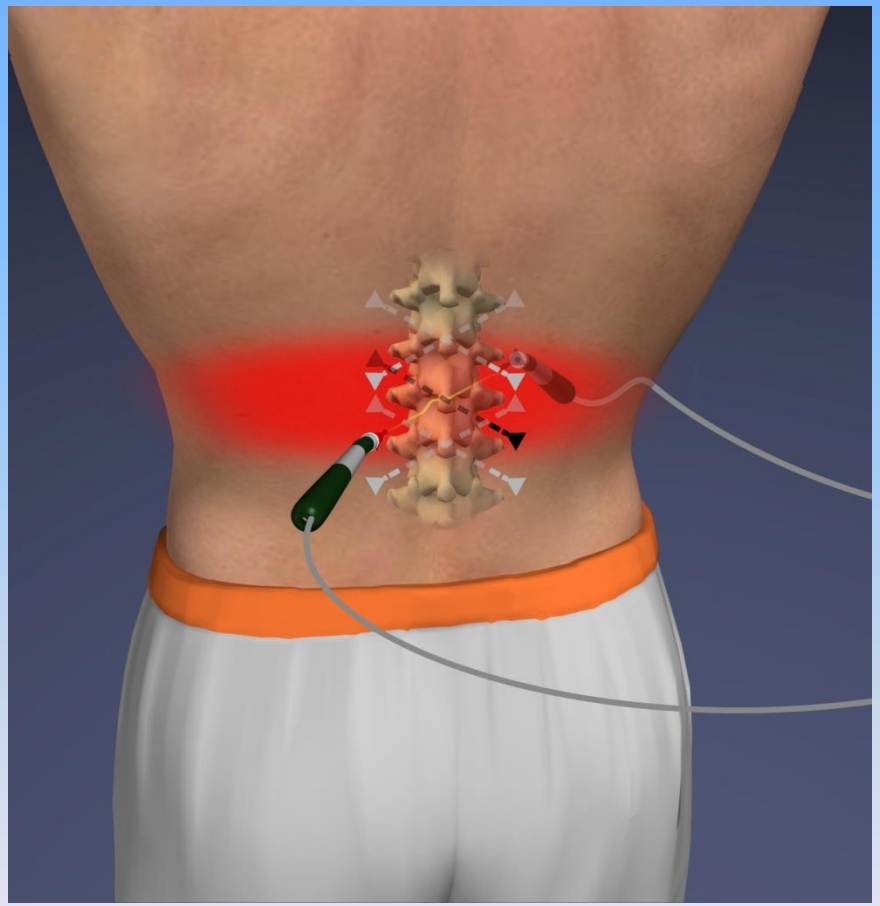
The Standard 2-Minute Protocol

Example 1: L.E. Pain (knee)

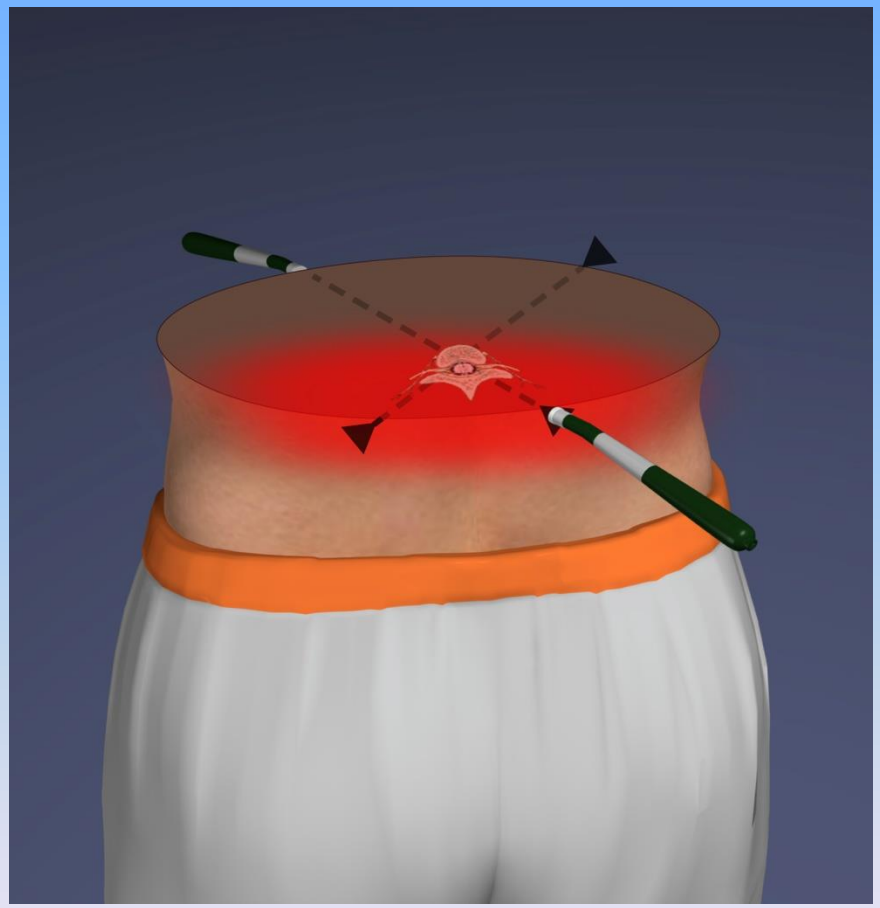
The Standard 2-Minute Protocol

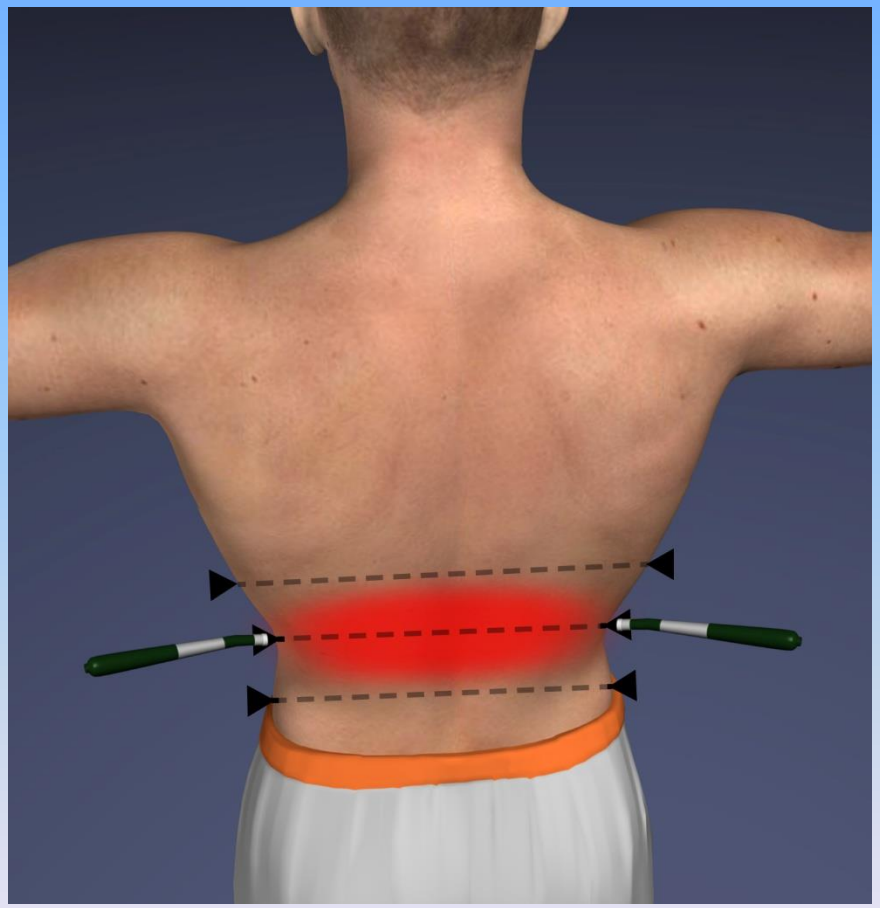
Example 2: Back Pain



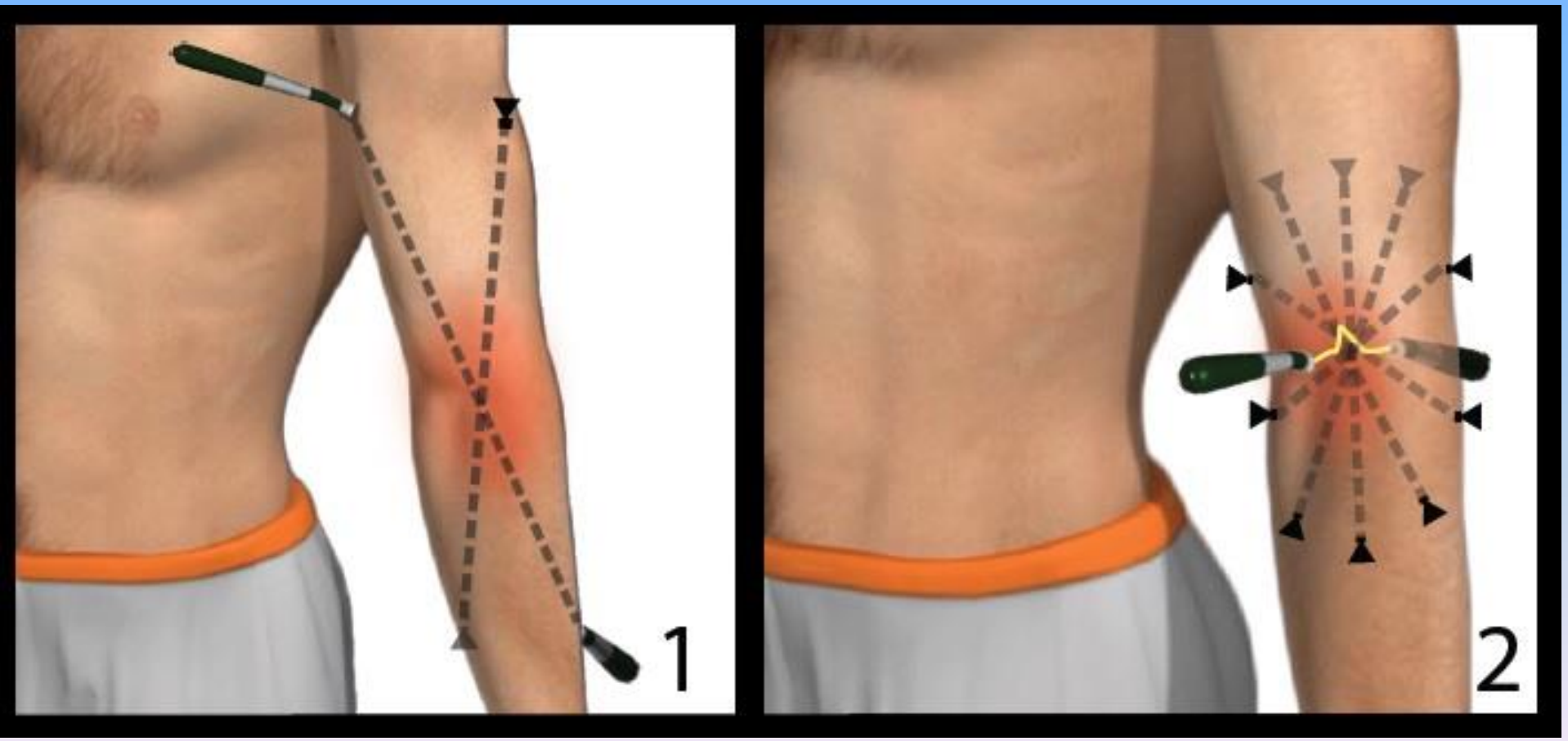


Example 2: Back Pain

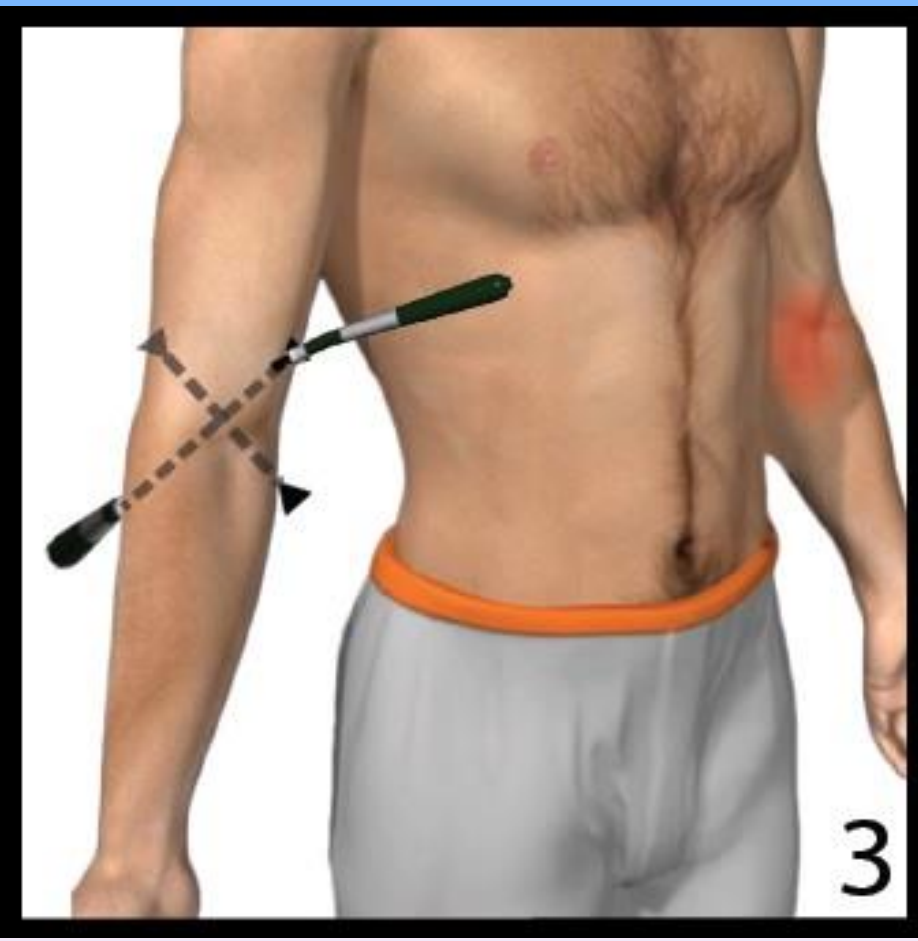


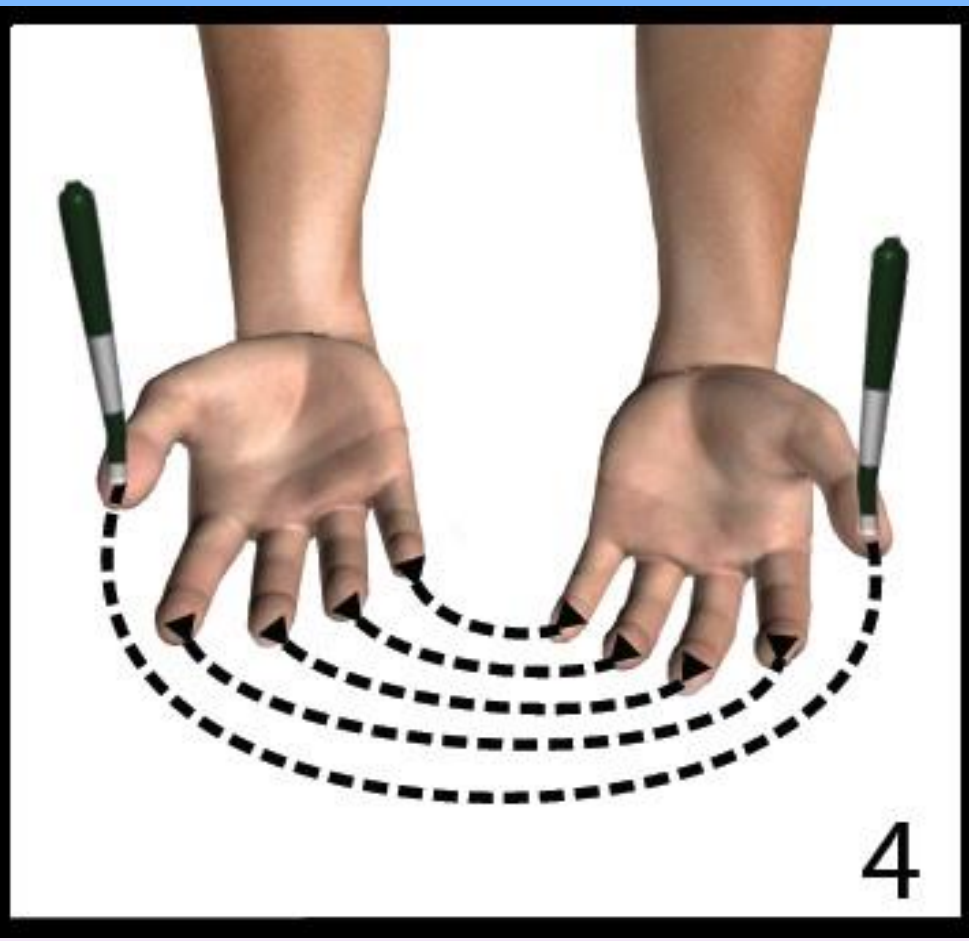


Example 4: Elbow Pain

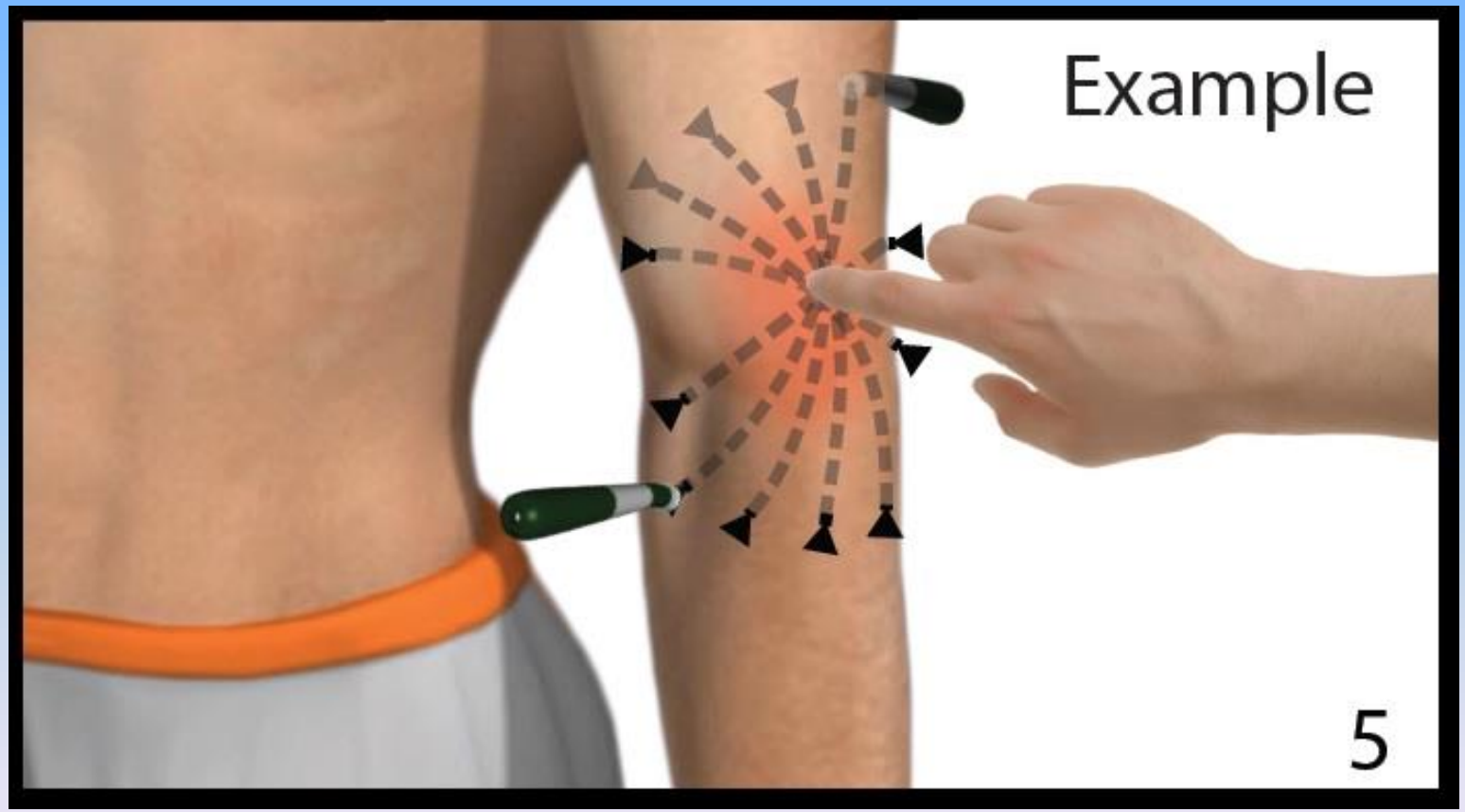


Example 4: Elbow Pain

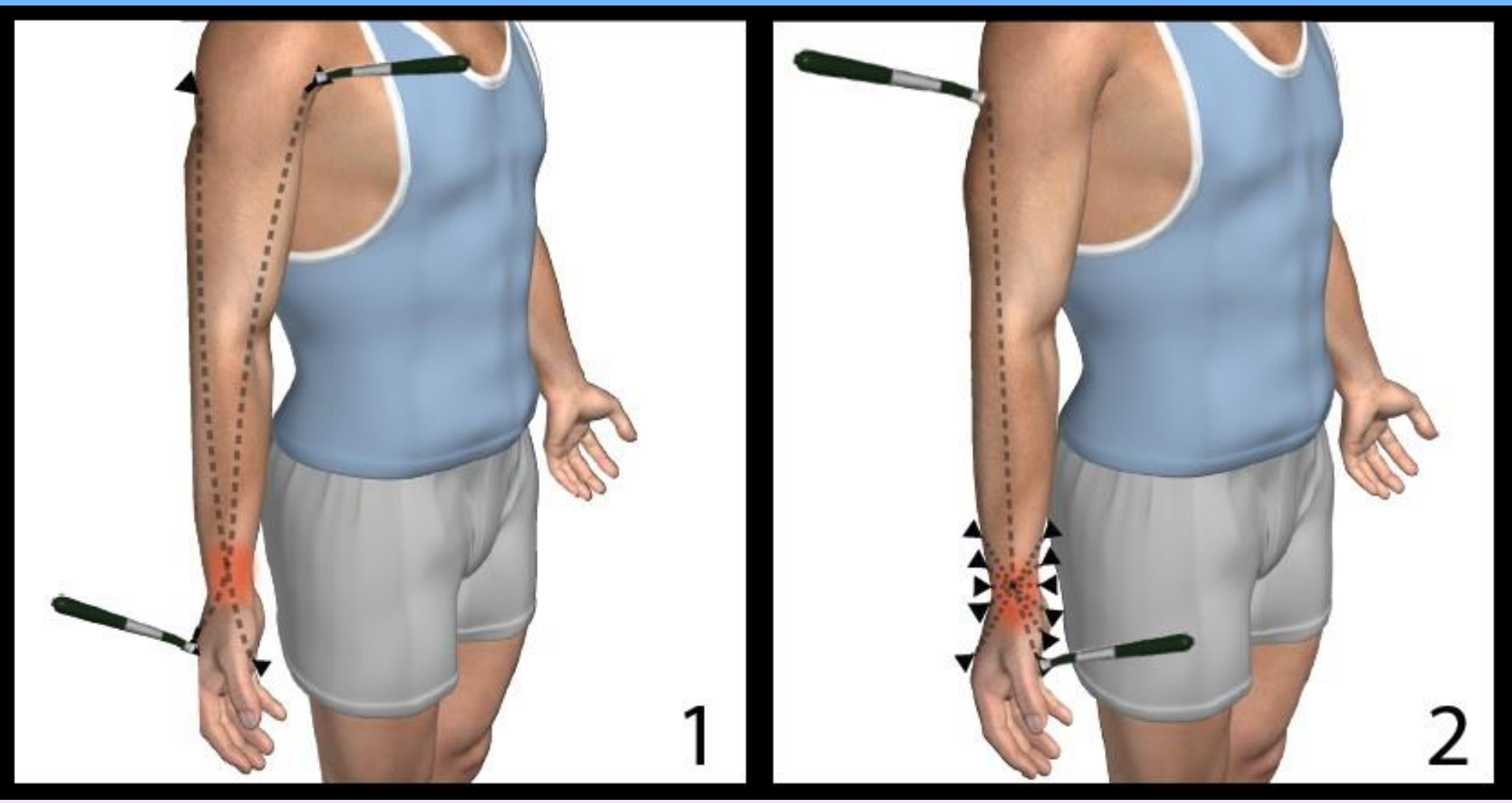




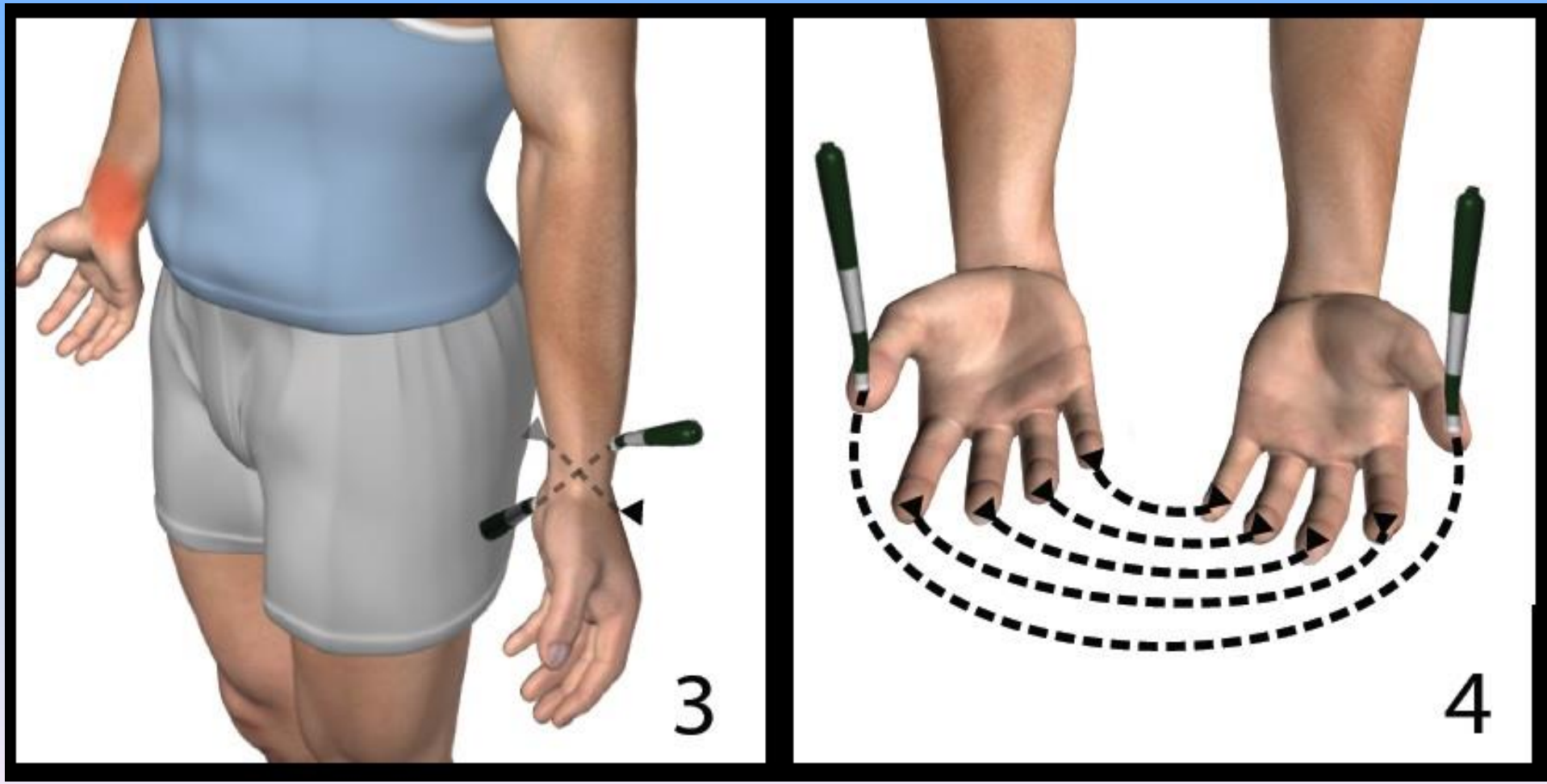
Example 4: Elbow Pain



Example 5: Wrist Pain



Example 5: Wrist Pain



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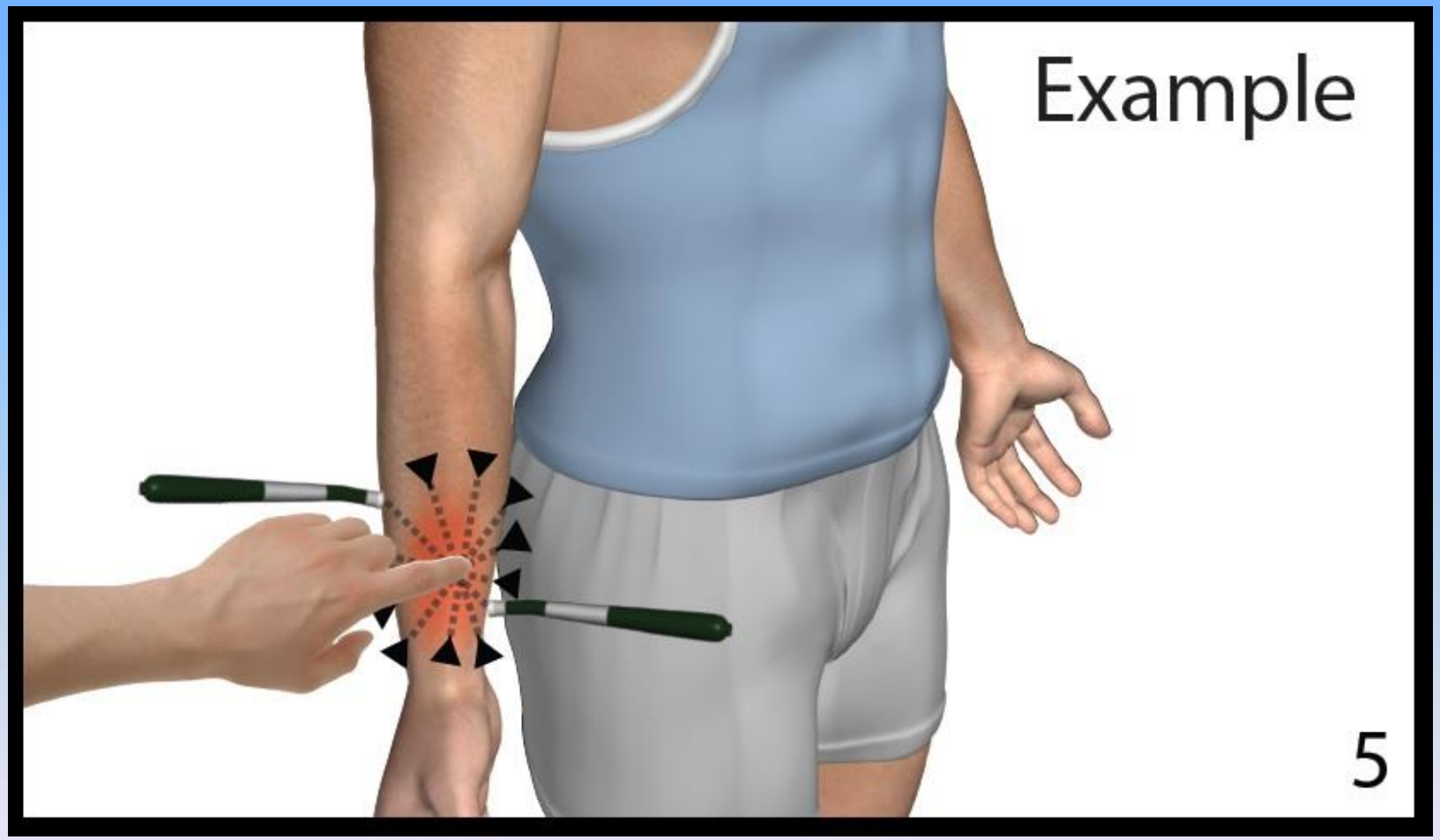

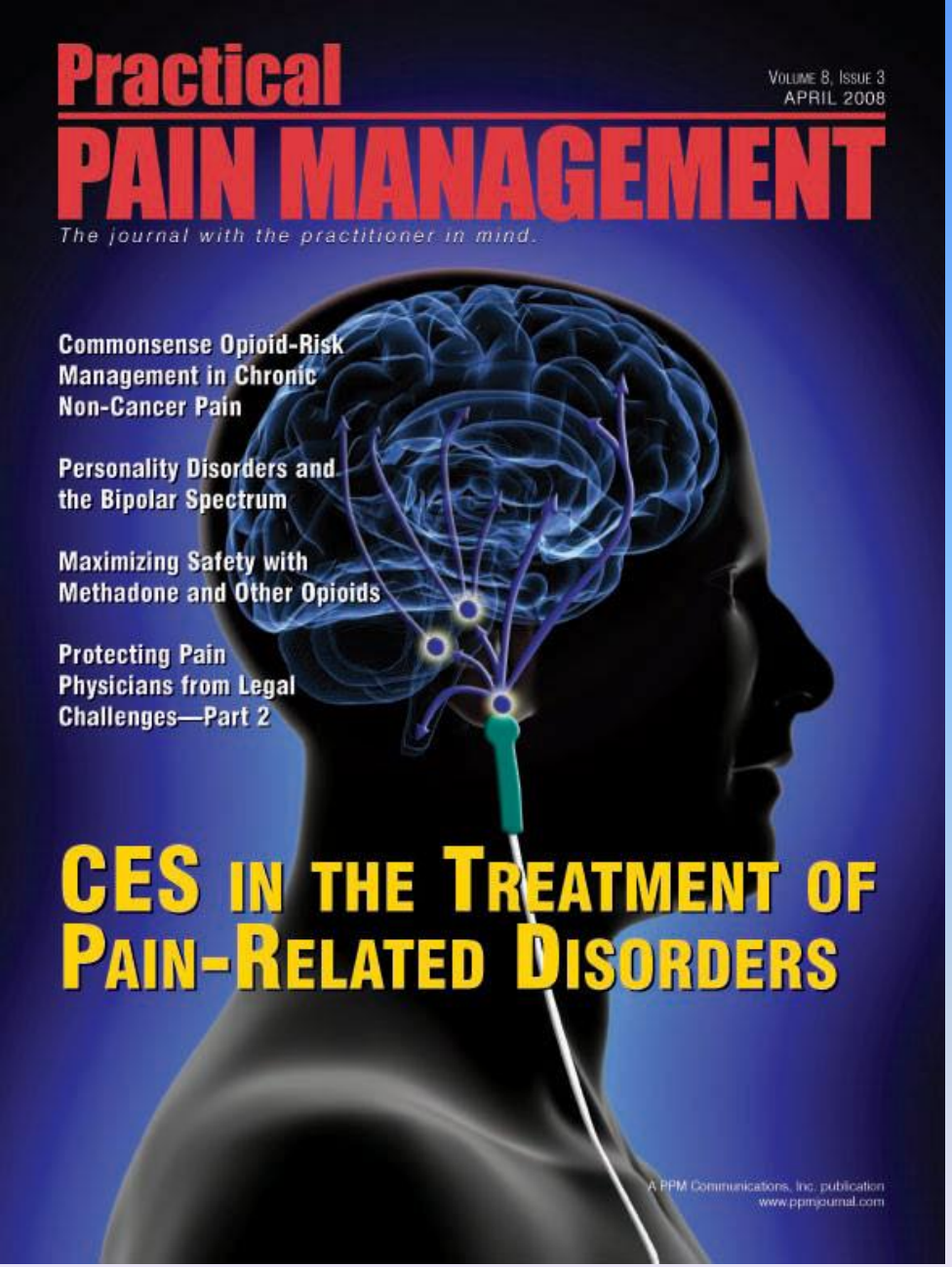

Kirsch, Daniel L. and Gilula, Marshall F. CES in the treatment of pain-related disorders. *Practical Pain Management*, 8(3):12-25, 2008

Don't Forget About the Brain

Always finish with at least 20 minutes of Alpha-Stim CES

Are Your Patients in Pain? Anxious? Depressed? Not Sleeping well? Why Not Try Alpha-Stim?

Questions? Call 1-800-FOR-PAIN

Email Dr. Steve Haltiwanger: steve@epii.com

www.alpha-stim.com