APPENDIX A. SEARCH STRATEGIES

CRANIAL ELECTRIC STIMULATION – SEARCH METHODOLOGY

DATABASE SEARCHED: PubMed

SEARCH STRATEGY #1:
TIME PERIOD COVERED: from inception to 2/1/2016
LANGUAGE: English

"cranial electrical stimulation"(tiab) OR cranial electric stimulat*(tiab) OR electrotherap*(tiab) OR fisher wallace stimulat*(tiab) OR alpha-stim(tiab)

SEARCH STRATEGY #1A (update to Search #1):
TIME PERIOD COVERED: 1/1/2016-7/12/2017
LANGUAGE: English

"cranial electrotherapy" OR cranial electric stimulat* OR cranial electrical stimulat* OR alpha-stim OR fisher wallace stimulat*

SEARCH STRATEGY #2:
TIME PERIOD COVERED: from inception to 7/12/2017
LANGUAGE: ALL

Electrosleep OR "Transcerebral electrotherapy" OR "Neuroelectric therapy"

SEARCH STRATEGY #3:
TIME PERIOD COVERED: from inception to 7/17/2017
LANGUAGE: English

Similar Article searches on the following articles:
A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression
Timothy H. Barclay a,n, Raymond D. Barclay b, Journal of Affective Disorders 164 (2014) 171–177

Alfred G. Bracciano , Wen-Pin Chang , Stephanie Kokesh , Abe Martinez ,Melissa Meier & Kathleen Moore (2012) Cranial Electrotherapy Stimulation in the Treatment of Posttraumatic Stress Disorder: A Pilot Study of Two Military Veterans, Journal of Neurotherapy, 16:1, 60-69, DOI: 10.1080/10874208.2012.650100 –
NOT IN PUBMED

Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study
R. Gregory Lande,∗, Cynthia Gragnanib
Complementary Therapies in Medicine (2013) 21, 8—13

Cranial electrical stimulation improves symptoms and functional status in individuals with fibromyalgia

Cranial electrical stimulation improves symptoms and functional status in individuals with fibromyalgia
Taylor, A. G., Anderson, J. G. Riedel, S. L. Lewis, J. E. Kinser, P. A. Bourguignon, C.
Pain Manag Nurs, (2013) 14(4), 327-335

SEARCH STRATEGY #4:
TIME PERIOD COVERED: from inception to 10/10/17
LANGUAGE: English

"transcranial electrical stimulation"(Title) OR "transcranial electric stimulation"(Title)

DATABASE SEARCHED: PsycINFO

SEARCH STRATEGY #1
TIME PERIOD COVERED: from inception to 2/4/2016
LANGUAGE: English

S1 TI ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical stimulation") OR SU ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical stimulation") OR AB ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical stimulation") OR (SU electrical stimulation AND (brain OR cranial OR transcranial))
AND
TI (pain OR painful OR depression OR depressive OR anxiety OR anxiety disorders(mh) OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia) OR SU (pain OR painful OR depression OR depressive OR anxiety OR anxiety disorders(mh) OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia) OR AB (pain OR painful OR depression OR depressive OR anxiety OR anxiety disorders(mh) OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia)

OR

TI ("fisher wallace stimulation" OR alpha-stim) OR SU ("fisher wallace stimulation" OR alpha-stim) OR AB ("fisher wallace stimulation" OR alpha-stim)

SEARCH STRATEGY #1A (update to Search #1):
TIME PERIOD COVERED: 1/1/2016-7/12/2017
LANGUAGE: English

TI ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical stimulation") OR SU ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical

stimulation") OR AB ("cranial electrotherapy" OR "cranial electric stimulation" OR "cranial electrical stimulation") OR SU (electrical stimulation AND (brain OR cranial OR transcranial)) OR TI ("fisher wallace stimulation" OR alpha-stim) OR SU ("fisher wallace stimulation" OR alpha-stim) OR AB ("fisher wallace stimulation" OR alpha-stim)
AND
TI (pain OR painful OR depression OR depressive OR anxiety OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia) OR SU (pain OR painful OR depression OR depressive OR anxiety OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia) OR AB (pain OR painful OR depression OR depressive OR anxiety OR post-traumatic stress OR posttraumatic stress OR "post traumatic stress" OR ptsd OR insomnia OR sleep* OR fibromyalgia)

SEARCH STRATEGY #2:
TIME PERIOD COVERED: from inception to 7/12/2017
LANGUAGE: ALL

TI (Electrosleep OR "Transcerebral electrotherapy" OR "Neuroelectric therapy") OR SU((Electrosleep OR "Transcerebral electrotherapy" OR "Neuroelectric therapy") OR AB ((Electrosleep OR "Transcerebral electrotherapy" OR "Neuroelectric therapy")

SEARCH STRATEGY #3:
TIME PERIOD COVERED: from inception to 10/10/17
LANGUAGE: English

TI ("transcranial electrical stimulation" OR "transcranial electric stimulation")

DATABASE SEARCHED: Cochrane databases

SEARCH STRATEGY
TIME PERIOD COVERED: from inception to 2/4/2016
LANGUAGE: English

SEARCH STRATEGY #1
("cranial electrotherapy" or "cranial electric stimulation" or "cranial electrical stimulation":ti,ab,kw) OR (electrical stimulation and (brain or cranial or transcranial)):ti,ab,kw OR ("fisher wallace stimulation" or alpha-stim):ti,ab,kw (Word variations have been searched)
AND
pain or painful or depression or depressive or anxiety or anxiety disorders (mh) or post-traumatic stress or posttraumatic stress or "post traumatic stress" or ptsd or insomnia or sleep* or fibromyalgia:ti,ab,kw (Word variations have been searched)

SEARCH STRATEGY #1A (update to Search #1)
DATABASE SEARCHED: Cochrane CENTRAL

TIME PERIOD COVERED: 1/1/2016-7/12/2017

LANGUAGE: English

'"cranial electrotherapy" or "cranial electric stimulation" or "cranial electrical stimulation" in Title, Abstract, Keywords

SEARCH STRATEGY #2:
TIME PERIOD COVERED: from inception to 10/10/17
LANGUAGE: English

"transcranial electrical stimulation" or "transcranial electric stimulation" in Record Title

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DATABASE SEARCHED: Embase

SEARCH STRATEGY #1:
TIME PERIOD COVERED: From inception to 7/12/2017
LANGUAGE: English

'cranial electrotherapy' OR 'cranial electric stimulation' OR 'cranial electrical stimulation' OR 'fisher wallace stimulation' OR 'alpha stim'/exp OR 'alpha stim'
AND
(humans)/lim

SEARCH STRATEGY #2:
TIME PERIOD COVERED: from inception to 7/12/2017
LANGUAGE: ALL

'electrosleep'/exp OR electrosleep OR 'transcerebral electrotherapy' OR 'neuroelectric therapy'
AND
(humans)/lim

SEARCH STRATEGY #3:
TIME PERIOD COVERED: from inception to 10/10/17
LANGUAGE: English

'transcranial electrical stimulation':ti OR 'transcranial electric stimulation':ti

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NOTE: ADDITIONAL FILTERS FOR ANIMAL-ONLY STUDIES WERE APPLIED IN ENDNOTE

APPENDIX B. CRITERIA USED IN QUALITY ASSESSMENT

The Cochrane Collaboration's Tool for Assessing Risk of Bias*

Domain	Support for judgement	Review authors' judgement
Selection bias.		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
Performance bias.		
Blinding of participants and personnel *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
Detection bias.		
Blinding of outcome assessment *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.
Attrition bias.		
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Attrition bias due to amount, nature or handling of incomplete outcome data.
Reporting bias.		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.
Other bias.		
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Bias due to problems not covered elsewhere in the table.

* http://handbook.cochrane.org/ in Table 8.5.a

APPENDIX C. PEER REVIEW COMMENTS AND AUTHOR RESPONSES

Comments	Response
Page 18: Research gaps/future research: It might be useful to highlight the need for understanding whether possible benefits persist after treatment discontinuation or whether relapse in symptoms occur. In addition, there also is a need for comparative effectiveness research (rather that studies of "usual care" which evolves over time. VA is investing in dissemination of interventions for PTSD, depression and insomnia. An important question is whether CES is comparable to other evidence based treatments. Finally, quality of life outcomes should be incorporated into future research. This may be worthy of mention in this section of the review as well.	We have added these helpful suggestions to the future research section.
The study will be of significant value to providers in Pain Management as we discuss with our patients treatment options. Management of chronic pain is founded on a biopsychosocial model of pain. Treatment is often multimodal. While complementary and non-traditional approaches may have their value as one part of the pain management armamentarium, the many choices available nowadays may appear overwhelming to the medical providers and patients. Thus it is important to guide patients to the treatment options that have good evidence of effectiveness and a favorable benefit versus risk ratio. There are evidence-based pain behavioral pain management options (such as Cognitive Behavioral Therapy for Chronic Pain (CBT-CP), as well as physical therapy and other rehabilitation approaches with proven long-term benefit. It is important that “newer” pain management approaches such as CES do no distract patients from engaging in the therapeutic modalities that have much greater evidence of long term benefit. In regard to long-term risks of CES, the current evidence is rather sparse. While this systematic review indicates low evidence that CES does not cause serious side effects. It remains concerning that the older literature reference cited (reference 23, Feighner et al, 1974) reports “massive worsening of depressive symptoms” from so-called “electrosleep therapy”. We need long-term studies include appropriate measurements of mood and cognitive function, with adequate sensitivity for change of time, in order to conclude that gradual changes in these functions and other adverse effects do not occur over time.	We have added to the future research section the need for long-term studies of safety.
The systematic review does not make recommendations about use of CES in daily practice, and it will be interesting to see whether the information of this review will lead to any policy changes in VHA.	
In the reference to the Cochrane review by Kavirajan, page 2 line 44, the author's name is misspelled (should be "Kavirajan"). In addition, the lack of eligible studies in that Cochrane review was not due solely to the lack of trials with credible blinding in the sham group. Rather, some trials were excluded due to failure to use validated diagnostic criteria or rating scales. Additionally, since the review focused on acute major depression, which is the focus of clinical trials of most FDA-approved antidepressant agents, trials examining CES in chronic depression or treatment refractory depression or bipolar depression were excluded. So, the current characterization of the negative findings by Kavirajan et al is somewhat inaccurate. It could be corrected by stating that "a more recent Cochrane review of CES in acute uncomplicated by Kavirajan and colleagues3 restricted their eligibility criteria to RCTs with a convincing sham, diagnosis using standardized criteria, and assessments with validated rating instruments, reported finding no studies meeting these criteria."	We have made this correction.

The discussion of trials for "anxiety and depression" should state what specific anxiety disorders were examined, as anxiety is a symptom of various anxiety disorders and not a diagnosis in itself. The discussion should note which anxiety disorders were diagnosed using which criteria. In most of the trials considered (other than Barclay et al), it is unclear whether formal diagnostic criteria were used in the inclusion criteria and this should be noted in the text.	We have added text about this. Three of these studies were old (more than 40 years) and as noted by the reviewer, the diagnostic criteria used were either not stated or no longer considered current. Only in the study by Barclay and colleagues were formal modern criteria used (DSM-IV, SCID-I and the HAM-A scale).
Finally, there is a typo on page 2, line 19: "become" should be "became".	This was fixed.

APPENDIX D. EVIDENCE TABLE FOR RCTS OF CRANIAL ELECTRICAL STIMULATION BY CONDITION

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Painful Conditions							
• Migraine Headache o Fisher Wallace							
Tietjen, 2013[12]	"Chronic migraine without satisfactory pain control on medication" (No other details available)	This study used the Fisher-Wallace Cranial Stimulator, a low-intensity alternate current device.	Not described other than "sham".	50	1 month	Assessment of blinding not performed	Pre-Treatment mean headache days CES: 19.4 Sham: 19.6 Post-treatment mean headache days CES: 18.5 Sham: 20.1 (No significant difference)
• Headache o Pain Suppressor							
Solomon, 1985[19]	Adults with migraine or muscle contraction headaches or both. (No other data provided)	This study used the Pain Suppressor. It was a low amperage (maximum 4 mA), high frequency (12,000 to 20,000 Hz rectified to monophasic wave form) and short pulse width (approximately 30 ms).	The subliminal CES used electric current just below the patient's ability to experience the tingling sensation. The placebo had electrodes in place without electrical stimuli.	40	1 treatment	Assessment of blinding not performed	Improved symptoms of headache CES: 10 of 18 (55%) Subliminal CES: 5 of 18 (28%) Sham: 4 of 22 (18%) ($p < .025$)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Solomon, 1989[13]	Adults with tension headaches occurring alone or as part of migraine. Patients with a diagnosis of migraine headache, cluster headache, or medication rebound headache were excluded. Mean age = 42 % female = not reported	This study used the Pain Suppressor. The intensity of the electrical current was adjustable from 0-4 mA. Patients were instructed to increase the intensity until a sensation was felt at the electrode site. The intensity was further increased to the maximum tolerable level, defined as that point where the tingling sensation due to the current became uncomfortable. The unit delivered the current for 20 minutes before shutting off automatically. The signal consisted of a monopolar square wave pulse with a duration of 35 µs a peak amplitude of 4 mA. The pulse was repeated at a frequency of 15,000 Hz for 50 ms. The 50 ms pulse train had a repetition rate of 15 Hz.	The placebo current ran for 70 seconds before shutting off, but the current meter registered 1.0 – 4.0 mA for 20 minutes, the same as the active unit.	100	10 weeks	Assessment of blinding not performed	Global evaluation by patient Highly effective CES: 6 (12%) Placebo: 2 (4%) Moderately effective CES: 12 (24%) Placebo: 6 (12%) Minimally effective CES: 13 (26%) Placebo: 20 (20%) Not effective CES: 19 (38%) Placebo: 31 (63%) (p = .006)
• Degenerative Joint Disease o Alpha-Stim							
Heffernan, 1997[20]	30 subjects were chosen, half females, half males, aged 30-65 years, who were experiencing DJD of hip, shoulder, knees, or back, confirmed by x-ray, and whose pain was unresponsive to medication, and lasted for at least 8 hours per day for 2 years or more.	[This] … device provided a variable, averaged, 0.5 Hz, biphasic square wave pulse, at a 50% duty cycle.	The control device was a function generator producing a constant 0.5 Hz square wave, at 50% duty cycle.	30	1 treatment	Assessment of blinding not performed	Pre-treatment mean pain score (0-5) CES: 4.5 Control: 4.6 Post-treatment CES: 2.1 Control: 4.8 (p < .01)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
	o Custom-built device						
Katsnelson 2004 [22]	Adults with hip or knee osteoarthritis with baseline pain score >4 Mean age = not stated % female = 97%	The device for this study was custom-built by the authors. It can deliver 1-15 mA RMS of a modulated, 100kHz AC waveform. The waveform can be symmetric or asymmetric.	The sham device delivered no therapeutic current	64	5 days	Assessment of blinding not performed	Pre-treatment mean VAS pain score (0-10) Sham: 5.8 Symmetric: 5.8 Asymmetric: 6.0 Post-treatment mean VAS pain score Sham: 3.6 Symmetric: 2.9 Asymmetric: 3.0 (p>0.05)
• Fibromyalgia o Alpha-Stim							
Lichtbroun, 2001[15]	Adults from a single practice diagnosed by one clinician as having fibromyalgia using ACR criteria Mean age = 50 % female = 97%	This study used the Alpha-Stim device. Each device was preset to provide 100-µA, modified square-wave biphasic stimulation on a 50% duty cycle at 0.5 Hz, and to automatically turn off at the end of the hour.	Sham treatment was identical (except) electrodes did not pass current.	60	3 weeks	Assessment of blinding not performed	"The double-blind treated group had significant mean gains on tender point score ($t = 2.27$, $p < .01$), self-rated pain ($t = 3.04$, $p < .002$), quality of sleep ($t = 2.05$, $p < .02$), feeling of well being ($t = 1.67$, $p < .05$), and quality of life ($t = 1.92$, $p < .03$). There were 38 degrees of freedom on each analysis. The sham-tested and placebo-controlled groups had no positive gains during the study." (No two-tailed test of statistical significance was performed comparing active with sham CES treated patients.)
Cork, 2004[21]	Adults 22-75 years of age presenting to a university pain clinic with a diagnosis of fibromyalgia Mean age = 53 % female = 95%	All patients were given an Alpha-Stim CES device. Each devise was preset to provide 1 hour of 100-µA, modified square-wave biphasic stimulation on a 50% duty cycle at 0.5 Hz.	Sham treatment was provided by identical ear clips that did not pass current	74	3 weeks	Assessment of blinding not performed	Pre treatment pain intensity (0-5) CES: 3.4 Sham: 3.6 Post-treatment pain intensity CES: 2.5 Sham: 3.4 ($p < .01$)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Taylor, 2011[9] Taylor, 2013[14]	Adult patients were recruited from local rheumatology practices and were eligible if they met ACR 1990 criteria for fibromyalgia and had a score of 3 or greater on a 10 point number rating scale and were on stable medication for at least 4 weeks. Mean age = 51 % female = 94% Mean pain = 5.8	This study used the Alpha-Stim device. Participants in the CES device group received devices that were active and preset at the factory to provide a maximum of 60 minutes of modified square-wave biphasic stimulation at 0.5 Hz and 100 mA, the lowest setting that has been used in earlier studies with patients with FM and below the level of perception.	Sham devices appeared to be activated, but did not deliver any stimulation.	46	8 weeks 8 weeks	Assessment of blinding not performed	Pre-treatment pain CES: 5.8 Sham: 5.7 Usual care: 6.0 Post-treatment pain CES: 5.0 (estimated) Sham: 5.9 (estimated) (Slope of line was stated as statistically different between groups, but comparison of final outcomes across groups was not performed)
• Spinal Cord Injury o Alpha-Stim							
Tan, 2006[17]	Veterans who were 6 months to 60 years post-SCI with chronic musculoskeletal pain or neuropathic pain, without evidence of substance abuse or severe cognitive or mental disorder. Mean age = 56 % female = 0% 55% had neuropathic pain	This study used the Alpha-Stim 100 with "the amount of electrical stimulation set at a sub-threshold level and could not be changed by the participant."	Sham CES, not otherwise described.	38	21 days	Assessment of blinding not performed	Average daily pain ratings Pre-treatment CES: 6.5 Sham: 6.1 Post-treatment CES: 5.7 Sham: 6.0 (The authors did not do tests of between group ratings)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Tan, 2011[16]	VA patients with SCI (any level and any degree of completeness) that had occurred at least 6 months prior, and having at least one chronic pain component at or below the level of the injury that was classified as neuropathic pain and ≥ 5 on a numeric rating scale. Mean age = 52 % female = 14%	This study used the Alpha-Stim SCS. Persons in the treatment group received 1 hour per day of 100 µA sub-sensation active CES.	The control group received sham CES for the same amount of time.	105	21 days	Assessment of blinding not performed	Pre-treatment pain CES: 5.60 Sham: 5.41 Post-treatment pain CES: 5.00 Sham: 5.00 (p > .90)
• Neuromuscular pain lasting > 6 months o Alpha-Stim							
Tan, 2000[18]	VA patients with primarily neuromuscular pain of at least 6 months duration. Patients with fibromyalgia, history of significant exposure to electricity and chronic psychiatric problems were excluded. Mean age = 56 % female = 9% Back pain was the most common symptom.	This study used the Alpha-Stim 100. This equipment uses a battery to deliver 10 to 600 microamperes of adjustable current at selected frequencies of 0.5, 1.5, or 100 Hz. For this study, 0.5 Hz was the selected frequency used.	In the sham, brief electrical stimulation was provided in random order.	11 (28 began treatment, there were 17 dropouts)	12 treatments over a variable period of time	Assessment of blinding not performed	No significant differences in slope of pain scores over time between active and sham CES using ANOVA.

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
• Musculoskeletal pain lasting > 6 months in Parkinson's patients o Alpha-Stim SCS							
Rintala, 2010[23]	VA and non VA patients with Parkinson's disease and chronic musculoskeletal pain or low or extremity pain of at least 6 months duration with average pain intensity of at least 5 of 10.	The CES equipment used was the Alpha-Stim SCS. Active devices provided subsensory stimulation of 100 mA.	Sham devices had no electric current flowing	19	42 days	Assessment of blinding not performed	Differences between active and sham CES before and after the 42 day treatment period were not statistically tested. Pre/post treatments within each treatment day favored active CES treatment.
• Cervical pain, chronic low back pain, or headaches o Transcranial ElectroStimulator							
Gabis, 2003[24]	Adult patients with chronic low back or cervical pain seen in a pain clinic Mean age = 46.2 % female = 55% 85% of patients had back pain	This study used the Transcranial ElectroStimulator Pulsatilla 1000. The stimuli generator emits pulses on a fixed and controlled frequency. The maximal electrode current as measured on the forehead electrode is 4mA. The treatment is asymmetrical, biphasic for zero net charge, 77Hz frequency and 3.3 msec of pulse width	Patients receiving placebo were treated with a 50 Hz signal with maximum current of 0.75 mA. It was designed to give the patient the feeling of being treated	20	8 consecutive days	Assessment of blinding not performed	Mean difference pre-post treatment on VAS pain score CES: 2.2 Sham: 1.2 (not significant)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Gabis, 2009[25]	Adult patients with cervical pain, chronic low back pain, or headaches Mean age = 51 % female = 60%	This study used the Transcranial ElectroStimulator Pulsatilla 1000. The stimuli generator emits pulses on a fixed and controlled frequency. The maximal electrode current as measured on the forehead electrode is 4mA. The treatment is asymmetrical, biphasic for zero net charge, 77Hz frequency and 3.3 msec of pulse width	Patients receiving placebo were treated with a 50 Hz signal with maximum current of 0.75 mA. It was designed to give the patient the feeling of being treated	119	8 consecutive days of treatment 3 weeks and 3 months	Assessment of blinding not performed	Pre-treatment VAS pain scores Cervical pain CES: 5.89 Placebo: 5.65 LBP CES: 5.82 Placebo: 7.00 Headache CES: 6.20 Placebo: 4.59 3 week follow up Cervical pain CES: 3.26 Placebo: 4.65 LBP CES: 3.82 Placebo: 5.25 Headache CES: 3.55 Placebo: 3.73 (Comparison of headache pre-post p=0.007, all other differences not significant) At 3 months follow up all comparisons pre-post were statistically significant except patients with LBP

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Depression							
	o Fisher Wallace						
McClure, 2015[27]	Adults with bipolar depression diagnosed using SCID-P, not diagnosed as treatment-resistant, between HAM-D 13-28, CGI-S $\leq$ 5 Mean age = 48 % female = 50% 80% had comorbid personality disorder Mean HAM-D = 19.6	This study used the Fisher-Wallace Cranial Stimulator. It used alternating current in three frequencies: 5 Hz, 500 Hz, and 15,000 Hz. The CES treatment was delivered by two electrodes covered with damp sponges and placed over the temples bilaterally with 2 mA of alternating current for one 20-minute session per day for the active treatment group.	The sham CES treatment was performed by a trained technician who did not take part in any other aspect of the study, by turning the current on until the patient experienced a tingling sensation on the scalp, then turning it off.	16	12 weeks (double-blind phase = 2 weeks)	Assessment of blinding not performed	Pre-treatment HAM-D CES: 18.1 Sham: 20.7 Post-treatment HAM-D (2 weeks) CES: 10.9 Sham: 15.1 (p = .5) Pre-treatment BDI CES: 30.6 Sham: 29.6 Post treatment BDI (2 weeks) CES: 17.6 Sham: 25.9 (p=0.02)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Mischoulon, 2015[26]	Adults with major depressive disorder, treatment resistant on a stable dose of antidepressant medication HAM-D score of 15-23 Mean age = 48 Mean HAM-D = 18.4 % female = 57%	This study used the FW-100 Fisher Wallace Cranial Stimulator. The device's electronic waveform contains a 15,000 Hz (to traverse the skull) square wave carrier which is rectified, varying from 0 to 4 mA. The first 15 Hz modulating signal (to theoretically influence brain neurochemical activity) provides 50 ms of "on" time and 16.7 ms of "off" time (total pulse period 66.7 ms, 50% duty cycle). A second, 500 Hz modulating signal changes the "on" time series of 15,000 Hz carrier pulses (750 pulses in 50 ms) into 25 smaller bursts of 15 pulses each of the 15,000 Hz carrier signal, for 375 pulses in the same 50 ms. The consecutive positive burst and "off" time is followed by an equal and opposite negative burst and "off" time, balancing the direct current component to zero. Output voltage ranges from 0 to 40 V, first positive and then negative. CES was left at this level until it automatically shut off after 20 minutes.	The sham devices were modified to not deliver current to the headset.	30	3 weeks 3 weeks	Double Assessment of blinding not performed	Pre-treatment HAM-D CES: 18.1 Sham: 18.7 Post-treatment HAM-D CES: 15.8 Sham: 14.5 (no significant difference)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
	o Alpha-Stim						
Turner, 2016[28]	Adults self-referred by response to community advertisements with BDI-II of 14 or greater. Mean age = 60 Mean BDI-II = not stated % female = 90%	The cranial electrotherapy stimulation devices used in this study were furnished by Electromedical Products International. (The manufacturer) coded the devices prior to shipment. CES stimulation was administered for 60 minutes at an intensity of 2 V, which produced 100 mA at 0.5Hz random biphasic square wave form.	The placebo treatment earclips did not pass current	20	3 weeks	Assessment of blinding not performed	Average reduction in BDI, post-treatment compared to pre-treatment CES: 14.1 Sham: 11.1 (p=0.46)
• Anxiety & Depression o Alpha-Stim							
Barclay, 2014[7]	Adults meeting DSM-IV criteria for anxiety disorder and comorbid depression confirmed using SCID-I, HAM-D > 15, benzodiazepine use only if PRN and no more than 2 per week, patients with any other Axis I diagnosis were excluded, or at risk for suicide or attempted suicide in the prior 12 months. Mean age = 42 % female = 67.8% Mean HAM-A = 28.5 Mean HAM-D = 13.9	This study used the Alpha-Stim 100. The device provides electrical stimulation by generating bipolar, asymmetric, rectangular waves with a frequency of 0.5Hz and a current intensity that was preset and locked by the manufacturer at its lowest therapeutic doseat100 µA, a subsensory level.	The sham CES devices were identical to the active device, except the ear clip electrodes and did not transmit electricity.	115	5 weeks	Assessment of blinding not performed	Pre-treatment HAM-A CES: 29.5 Sham: 27.6 Post-treatment HAM-A CES: 13.4 Sham: 20.0 (p = 0.001) Pre-treatment HAM-D CES: 14.5 Sham: 13.2 Post-Treatment HAM-D CES: 6.5 Sham: 10.0 (p = 0.001)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
	o Neurotone 101						
Hearst, 1974[29]	Adult outpatients at a University psychiatric clinic who had been ill for at least two years without obtaining a definitive remission despite chemotherapy and psychotherapy, and with no change in treatment for at least 1 month. Psychotic patients were excluded. 50% had depression, 40 % had anxiety, and 36% had hypochondriasis. Mean age = 38 % female = 86%	This study used the Neurotone 101. Burst rate was 100 Hz/second with a burst width of 2 ms. This current was used to treat the alternating current treatment group.	The sham group consisted of altering the current from the Neurotone 101 to direct current, rectified and filtered to force positive square wave pulses of the same width and frequency.	28	5 days	Assessment of blinding not performed	Number of patients reporting greater than median improvement Depression CES: 79% Sham: 21% Anxiety CES: 29% Sham: 50% Hypochondriasis CES: 29% Sham: 43% (* $p < 0.05$ as reported in article) Number of patients "completely well" on overall global rating CES: 79% Sham: 50% (no significant difference)
Scallet, 1976[32]	Patients were included if they attended a university psychiatry outpatient clinic, had no change in medication, attending psychiatric or psychotherapeutic approach for at least 1 month, had a diagnosis of chronic hysteria, and no evidence of active medical or neurologic disease. Mean age and gender no reported.	The Neurotone 101 was used. The burst rate was 100 Hz/second with a burst width of 2 ms. The output was rectified and filtered to form positive square wave pulses of the same width and frequency.	All patients received relaxation technique instructions. The sham group had the amplitude of current reduced over 30 seconds and then discontinued, and was told that patients often develop a tolerance to the tingling sensation.	17	3 weeks	Assessment of blinding not performed	Change in symptom scores at 1 week Anxiety Relaxation + central stimulation CES: 5.4 Relaxation + peripheral stimulation CES: 7.7 Relaxation + sham: 1.4 ($p < 0.05$) Depression Relaxation + central stimulation CES: 5.4 Relaxation + peripheral stimulation CES: 77.3 Relaxation + sham: 3.4 ($p > 0.05$)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
	o Electrosone-50						
Rosenthal, 1972[31]	Patient selected from psychiatric outpatient clinics. 18 of 22 patients had a diagnosis of neurosis and personality disorder with prominent anxiety, depression, and insomnia. Mean age = 43 % female = not recorded	This study used an American-made machine modeled after the Russian Electrosone. A frequency of 100 positive pulses per second and a pulse duration of 1 ms with no base line d-c bias current. The current was regulated so that the patient felt a slight but not uncomfortable tingling sensation over his or her eyes or mastoid processes. This was usually produced by a current reading of 0.1 to 0.25 mA on the machine dial. Independent measurement, however, indicated that the true current was 0.5 to 1.2 mA.	Not described other than the sham patients did not feel the tingling sensation.	22	5 days	Assessment of blinding not performed	Psychiatrist-assessed outcomes Pre-treatment anxiety CES: 4.3 Sham: 4.4 Post-treatment anxiety CES: 1.4 Sham: 3.2 Pre-treatment sleep disturbance CES: 4.2 Sham: 4.2 Post-treatment sleep disturbance CES: 0.8 Sham: 3.5 Pre-treatment depression CES: 2.8 Sham: 3.6 Post-treatment depression CES: 1.0 Sham: 2.7 (All differences between CES and sham were statistically significant)

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Feighner, 1973[30]	Adults "ill for a minimum of 2 years with prominent anxiety, insomnia, and depressive symptoms. All had received extensive prior psychiatric care including psychotherapy, pharmacotherapy remissions, and in 4 cases ECT without significant recession" Mean age = 41 % female = 79%	This study used the Electrosone-50. A machine setting of 100 positive pulses/second of direct current was used, with a duration of 1/ms and zero bias baseline current. Amplitude was gradually raised to tolerance for each patient until the prickling sensation over the eyes became moderately uncomfortable (average meter reading ranged from 0.1 to 0.25 mA).	Sham treatments were identical including the brief raising of amplitude to reach a moderately painful prickling sensation, after which the amplitude was slowly turned to zero.	23	2 weeks 2 weeks	Double Assessment of blinding not performed	Pre-treatment Global ratings CES: Anxiety = 4.5 Depression = 4.0 Insomnia = 4.6 Sham: Anxiety = 4.4 Depression = 3.8 Insomnia = 4.6 Post-treatment Global ratings CES: Anxiety = 2.5 Depression = 2.8 Insomnia = 1.9 Sham: Anxiety = 4.0 Depression = 3.9 Insomnia = 4.4 (no between-group comparisons were performed)

PTSD – No studies of cranial electrical stimulation to treat PTSD were identified

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
Insomnia							
	o Alpha-Stim						
Lande, 2013[8]	Subjects were active-duty military personnel who had a score of 21 or greater on the Pittsburgh Insomnia Rating Scale Mean age = not reported, but 77% of patients were less than age 41 % female = 19% Mean Pittsburgh Insomnia Rating Scale score = 36	This study used the Alpha-Stim SCS. The manufacturer set the active devices at 100 µA, an imperceptible level of stimulation.	Sham was described as a non-functional CES device.	57 (13 did not complete all 5 sessions)	5 days	Assessment of blinding not performed	No statistically significant difference between groups in time to sleep, total time slept, and number of awakenings
	o Electrodorm 1						
Weiss, 1973[33] Cartwright, 1975[36]	"Insomniacs" recruited in a newspaper advertising, who had reported a latency to sleep onset of at least 60 minutes at least 3 times per week. Subjects underwent study in the sleep laboratory and only those that did not reach stage 2 sleep within 20 minutes and stage 4 sleep within 60 minutes were included. (No details about age, sex, or other demographics provided)	This study used the Electrodorm 1.	The sham treatment discontinued the current after the tingling sensation was felt.	10	24 days	Assessment of blinding not performed	Pre-treatment Latency of sleep onset CES: 60.8 Sham: 60.5 Post-treatment Latency of sleep onset CES: 10.6 Sham: 58.5 (No between group comparisons were performed) Two-year follow up of 5 patients reported 4 were able to fall asleep with little difficulty

Author Year	Patients	Description of CES	Description of Sham or Comparison	Sample Size	Duration	Assessment of Blinding	Results
• Anxiety & Insomnia o Neurotone 101							
Moore, 1975[34]	"Subjects were selected because they were suffering from persistent anxiety and insomnia and did not have evidence of a psychosis" Mean age = 38 % female = 47%	This study used the Neurotone, which gave an output of 100 positive pulses per sec, with a pulse duration of 2 ms, and a maximum potential of 20 v. The current was turned on and slowly increased until a tingling sensation was felt. It was increased until it became uncomfortable, then turned back until the sensation stopped. The latter reading was between the former two. For treatment, the current was maintained just below the threshold of the tingling sensation.	Sham treatment was conducted identically to active treatment except the current was turned back to zero.	17	5 days	Assessment of blinding not performed	Patient-completed Taylor's Manifest Anxiety Scale change between pre and post-treatment CES: -0.75 Sham: 2.55 (No statistical difference) Subjective anxiety CES: 0.37 Sham: 0.55 (No statistical difference) Subjective insomnia CES: 1.87 Sham: 0.44 (p reported as < 0.05)
• Anxiety o Alpha-Stim							
Gibson, 1987[35]	Subjects were non-paid volunteers who responded to advertisements in local newspapers…who scored 50 or above on the state anxiety scale of the State-Trait Anxiety Inventory and were considered as "anxious". Mean age = 37 % female = 50%	This Alpha-Stim 350 was selected for use because it uses a microampere, randomized biphasic direct current through remote electrodes.	These were 2 comparison groups: 1) 20 minutes of pre-recorded relaxation instructions 2) control of 20 minutes of neutral tape with the CES device turned off	64	1 treatment	Assessment of blinding not performed	State anxiety scores pre-treatment CES: 52.3 Relaxation: 52.9 Control: 53.2 Post-treatment CES: 30.1 Relaxation: 32.2 Control: 51.9 (p < 0.001)

APPENDIX E. CITATIONS OF FULL-TEXT EXCLUDES

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