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Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study☆

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KEYWORDS
Insomnia;
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Summary
Objectives: This pilot study examined the potential efficacy of cranial electric stimulation for the treatment of insomnia.
Design: The researchers tested the hypothesis through a randomized, double-blind, and placebo controlled clinical trial. The researchers approached eligible subjects who scored 21 or above on the Pittsburgh Insomnia Rating Scale. The researchers then randomly assigned the subjects to receive either an active or sham device. Each study subject received 60 min of active or sham treatment for five days. Following each intervention the subjects completed a sleep log, as well as three and ten days later.
Setting: The researchers conducted the study among active duty service members receiving mental health care on the Psychiatry Continuity Service (PCS), Walter Reed National Military Medical Center in Bethesda, MD.
Main outcome measures: The study's primary outcome variables were the time to sleep onset, total time slept, and number of awakenings as reported by the subjects in the serial sleep logs. The researchers identified a nearly significant increase in total time slept after three cranial electric stimulation treatments among all study subjects. A closer examination of this group revealed an interesting gender bias, with men reporting a robust increase in total time slept after one treatment, decay in effect over the next two interventions, and then an increase in total time slept after the fourth treatment. The researchers speculate that the up and down effect on total time slept could be the result of an insufficient dose of cranial electric stimulation.
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Nearly everyone can recall a particularly poor night's sleep. Perhaps a troubling day at work or an anxiety laded looming event launches incessant bedtime ruminations that prevent the peaceful prerequisite. Even so, for most people a restful night's rest is the norm. For another group, affecting anywhere from 10 to 35% 0f Americans, each night brings tossing, turning, and all manner of sleep related turmoil.[1] In the beginning, the insomniac probably turns to readily available home remedies and nonprescription retail nostrums. The failure of these interventions to produce

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a restorative night's sleep often drives the sufferer to consider other options.

When home remedies fail the chronic insomniac seeks relief most commonly from alcohol, prescription medications, or both. In one study, 15% of chronic insomniacs reported using alcohol to initiate sleep.[2] Prescription medication choices broadly include benzodiazepines, nonbenzodiazepines, and antidepressants. There appears to be a long term trend favoring antidepressants, perhaps out of concern for benzodiazepine misuse.[3] In a similar manner, prescriptions for nonbenzodiazepine sedative hypnotics surged 30-fold between 1994 and 2007, far outpacing benzodiazepine use.[4] The perpetual use of prescription medications, averaging nearly four years for some chronic insomniacs, bolsters the concern for misuse.[5] Another troubling trend is the association between sedative-hypnotic sleep medications and suicidality.[6]

Chronic insomnia by itself is bad enough but the suffering is greatly magnified when the condition coexists with another problem. Both sleep latency and short sleep each independently exacerbates depression and delays a return to a normal mood state.[7] A pattern of poor sleep preceding a traumatic event increases the likelihood of post-traumatic stress disorder (PTSD).[8] The increasing recognition of an association between insomnia, nightmares, and other sleep problems with suicidal ideation has positive clinical relevance.[9,10] Insomnia is also over represented among individuals with physical conditions such as heart disease, high blood pressure, stomach ulcers, and asthma.[11]

The pervasiveness of chronic insomnia, and concerns about long term medication use and misuse, inspires clinicians' interest in nonpharmacologic treatments. Of particular note are highly efficacious behavioral interventions such as stimulus control and sleep restriction.[12] Cognitive behavior therapy is another evidence based treatment for chronic insomnia.[13] Rigorous studies examining the plethora of complementary and alternative therapies for insomnia are few and far between. Where such studies exist, there is some evidence that acupressure, tai chi, and yoga may be effective insomnia treatments.[14]This study examines a relatively unusual treatment approach using cranial electric stimulation (CES). CES involves the administration of miniscule electrical currents, often no more than 1 or 2 mA, to the head of individuals suffering from depression, anxiety, and insomnia.[15] Using tiny amounts of electrical energy for therapeutic effect has a rich history but modern practices date to the mid-twentieth century. At that time, clinicians referred to the practice as electrosleep therapy. A small, early randomized controlled trial of electrosleep technology reported a transient improvement with insomnia but a worsening of primary depression.[16] In another study from the same era, a researcher conducted a small double blind study specifically examining the impact of electrosleep on sleep latency.[17] The researcher reported a significant decline in sleep latency and an overall improvement in sleep efficiency. Yet another study found electrosleep therapy ineffective.[18] A few years later, a small double blind study reported an enduring improvement among insomnia subjects from electrosleep therapy that lasted for two years after initial treatment.[19]

Researchers published a meta-analysis of ''the most carefully conducted randomized controlled trials of CES versus sham treatment''.[20] With that rigorous approach the researchers identified 18 studies. In all but two studies the researchers were not blinded. With that limitation in mind, the meta-analysis resulted in CES being superior to sham only for the treatment of anxiety. The controversy over the efficacy of CES continued when another group of researchers criticized the methodology of this meta-analysis.[21]

Interest in CES continues unabated. Review articles tout the benefits, emphasizing the safety of the clinical practice and suggesting a role in reducing long term medication use.[22] Another reviewer, while not specifically commenting on the efficacy of CES for insomnia, once again commented on the need for sound methodological research.[23] Researchers in another study mounted an effort in that direction and through a randomized, double-blind controlled, clinical trial reported a ''trend toward statistically significant differences in reports of daily disturbances of sleep...'' with active CES treatment.[24]

The investigators in this study used the Alpha-Stim SCS cranial electrotherapy stimulator manufactured by Electromedical Products International, Inc. (2201 Garrett Morris Parkway, Mineral Wells, TX 76067-9034). When used in clinical practice the Alpha-Stim SCS cranial electrotherapy stimulator produces asymmetric rectangular electrical waves with a pulsed frequency of 0.5 Hz/s and 10 to 500 μA continuously adjustable current. The current is transmitted from the device through wires that terminate in conductive ear clips. The ear clips are attached to the person's earlobes.[25]

The exact mechanism of action of CES is not fully understood. Researchers have theorized that CES may affect endorphin release or modulate neurotransmitter activity. Placement of the electrodes on the earlobes probably permits the microcurrent to travel across local cranial nerves to the brainstem, thalamus and cortex. Functional magnetic resonance imaging (fMRI) suggests that CES results in cortical deactivation in the midline prefrontal and parietal areas of the brain. Researchers speculate that the brain deactivation may decrease obsessive worry and increase focused attention.[26] Electroencephalographic analysis also suggests that CES decreases anxiety by increasing alpha waves.[27,28] Ruminations and anxiety both inhibit sleep and the putative mechanisms of action of CES on brain activity in decreasing both would suggest a favorable outcome for the chronic insomniac. The researchers' objective was to test the efficacy of CES for insomnia through a randomized, double-blind, and placebo controlled pilot clinical trial.

Method

The researchers conducted the study among active duty service members receiving mental health care on the Psychiatry Continuity Service (PCS), Walter Reed National Military Medical Center in Bethesda, MD. The PCS provides evidenced based care in a multidisciplinary setting for service members needing a partial hospital level of care. Common diagnoses include combat related post-traumatic stress disorder (PTSD), mood disorders, substance disorders, and to a lesser degree psychosis. The researchers' recruited subjects

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from March 2010 through January 2012.The researchers conducted this study using the Alpha-Stim SCS cranial electrotherapy stimulator. The researchers received both the active and sham devices through a Cooperative Research and Development Agreement approved by Electromedical Products International and Walter Reed National Military Medical Center (WRNMMC). WRNMMC's Institutional Review Board approved the study.

The device manufacturer preset and coded all CES devices to maintain a double blind trial. The unit's serial number was coded on a master list containing limited subject identifiers sufficient to match the randomly drawn unit with the subject. The researchers assigned subjects to a control or treatment group by randomly selecting a functional or non-functional CES device from a box containing 10 functional CES devices and 10 non-functional CES devices.

The researchers approached eligible subjects who scored 21 or above on the Pittsburgh Insomnia Rating Scale.[29] Subjects, determined by clinical evaluation and self-administered psychometric tests as actively suicidal, having a seizure disorder history, cardiac pacemaker, active vertigo, or pregnant were excluded from the study.After obtaining the subject's written consent, the researchers asked each study participant to complete a demographic questionnaire and a detailed sleep log. The researchers then randomly assigned the study subjects to receive either an active or sham device. Each device looked identical. The manufacturer set the active devices at 100 μA, an imperceptible level of stimulation. Both active and sham devices were preset by the manufacturer for 60 min of operation once started by the researchers.

Each study subject received 60 min of active or sham treatment for five days. Following each CES intervention the study subjects completed a sleep log. Following the fifth session of either active or sham treatment the subjects completed a sleep log at two follow up points, at three and ten days.The study's primary outcome variables were the time to sleep onset, total time slept, and number of awakenings as reported by the subjects in the serial sleep logs. The overall effect of CES at each post-treatment time point was analyzed using two-sample *t*-tests. Total sleep hours were examined using the Shapiro Wilk test and found to satisfy the assumption of normality. To explore treatment differences by gender, sleep outcomes were compared using two way analysis of variance. Statistical analysis was conducted using SPSS for Windows, version 19. The data were additionally analyzed through descriptive statistics, chi-square, and independent sample *t*-tests.

Results

A total of fifty-seven service members agreed to participate in the study (Fig. 1). All subjects scored 21 or greater ($n = 57$, 35.67 SD 8.47) on the PIRS. In terms of randomization, the researchers achieved a nearly even split between the treatment group ($n = 28$) and the control group ($n = 29$). The demographics and distribution of the treatment and control groups (see Table 1) mirrored the military personnel structure with mostly male, younger, enlisted subjects.

Table 1 Characteristics of military subjects ($n = 57$).

	Treatment $n = 28$ *n* (%)	Control $n = 29$ *n* (%)
Age		
18—20	0 (0)	3 (10.3)
21—25	12 (42.9)	9 (31.0)
26—30	5 (17.9)	4 (13.8)
31—35	1 (3.6)	3 (10.3)
36—40	4 (14.3)	3 (10.3)
>41	6 (21.4)	7 (24.1)
Gender		
Male	20 (71.4)	26 (89.7)
Female	8 (28.6)	3 (10.3)
Rank[a]		
E1—E4	11 (39.3)	14 (48.3)
E5—E9	12 (42.9)	10 (34.5)
O1—O3	2 (7.1)	1 (3.4)
O4—O6	3 (10.7)	4 (13.8)
Marital status		
Single	11 (39.3)	10 (34.5)
Married	11 (39.3)	11 (37.9)
Separated	3 (10.7)	3 (10.3)
Divorced	3 (10.7)	5 (17.2)
Service branch		
Army	18 (64.3)	17 (58.6)
Air force	5 (17.9)	3 (10.3)
Navy	3 (10.7)	4 (13.8)
Marines	1 (3.6)	1 (3.5)
Other	1 (3.6)	4 (13.8)
Combat experience		
Yes	12 (42.9)	14 (48.3)
No	16 (57.1)	15 (51.7)

[a] E1—E4, junior enlisted rank; E5—E9, noncommissioned officers; O1—O3, junior commissioned officers; 04—O6, senior commissioned officers.

Approximately half of the subjects reported combat deployments. Over three-quarters of the subjects ($n = 44$, 77%) completed the full five sessions, receiving either sham or active cranial electric stimulation. The thirteen subjects who completed less than five sessions most commonly quit from a lack of interest or hospital admission for non-study related conditions. Two subjects both, from the treatment group, reported minor side effects. One subject believed a single session worsened their sleep and one subject complained of a headache, also after one session.

When comparing the treatment and control groups, in terms of time to sleep onset, total time slept, and number of awakenings the only positive or nearly positive findings emerged in total time slept. In the sleep log, in terms of total time slept, subjects indicated the time they went to bed, the time they awakened, and estimated the number of hours actually asleep.

After three sessions of either sham or active CES, subjects in the treatment group reported a nearly significant increase ($p = .079$) in total time slept when compared to the baseline sleep log. The treatment group subjects averaged about 43 extra minutes total time slept when compared to control subjects who reported an average 19 min less total time slept (see Table 2). There were no significant

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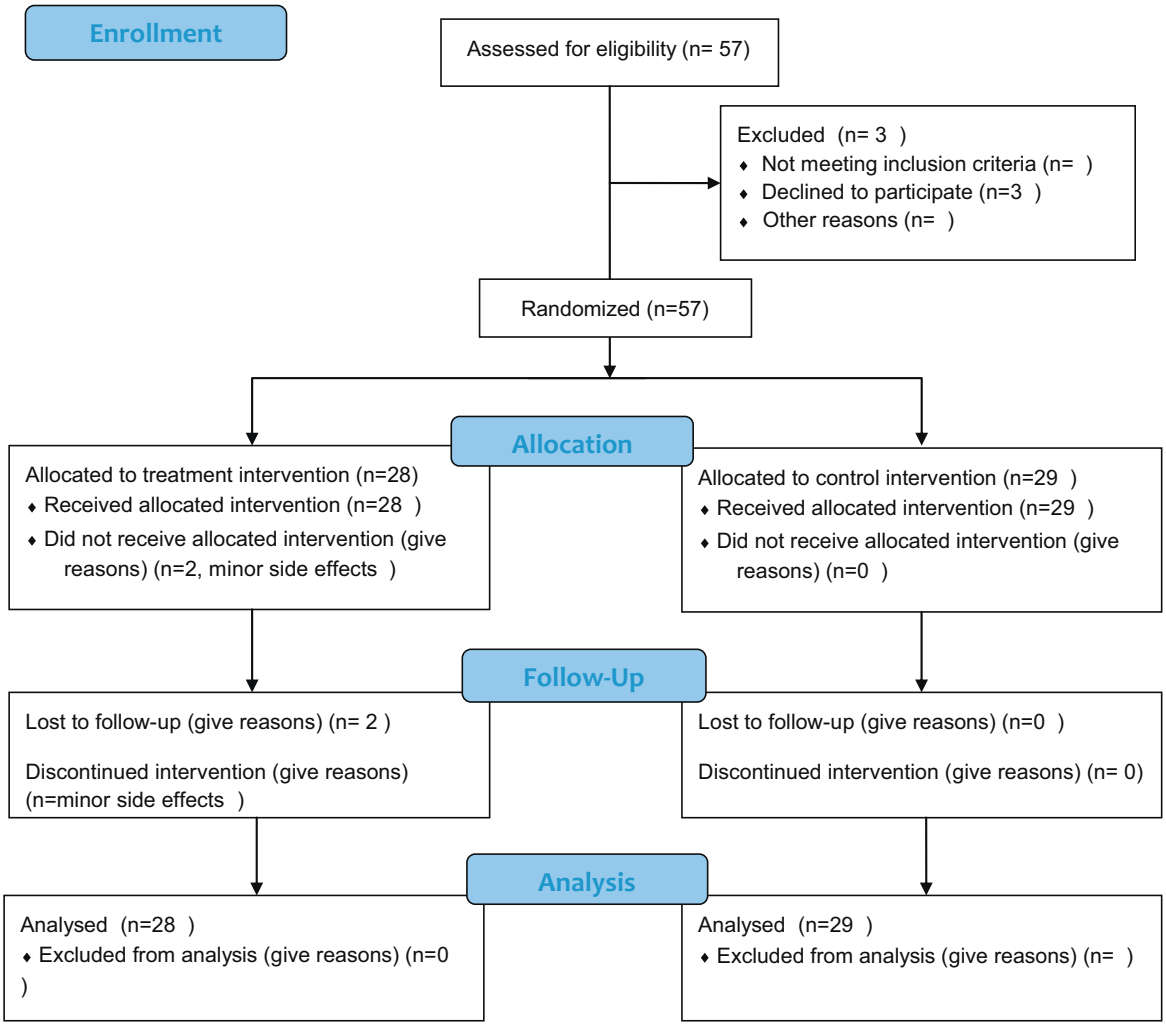

Fig. 1 CONSORT 2010 flow diagram.

differences between the treatment and control groups before or after this result.

In terms of estimating actual hours asleep, a significant gender difference (see Table 3) emerged. Men who completed five sessions of cranial electric stimulation reported a significant improvement in total time slept at two points in the study, after the initial ($p = .04$) and the fourth ($p = .03$) treatment when compared to their baseline sleep log. In other words, after the first CES treatment, men in the treatment group reported an average 53 min more total time slept when compared to the male control sample. In a similar fashion, after the fourth treatment men in the treatment group reported an average 61 min more total time slept when compared to the male control sample This positive trend did not extend to the three and ten day follow up sessions. There were no significant changes among the females.

Table 2 Change in hours in sleep time from baseline among all subjects who completed five sessions.

Data from	Treatment group			Control group			Mean difference (95% CI)	Sig 2-tailed
	N	Mean	SD	*N*	Mean	SD		
Day 2	15	1.05	2.05	21	.35	1.39	.70 (−.45805, 1.8676)	.277
Day 3	16	.26	1.58	20	−.52	2.45	.78 (−.66220, 2.2185)	.280
Day 4	16	.71	1.55	22	−.32	1.83	1.0 (−.12271, 2.1670)	.079
Day 5	16	1.03	2.54	20	.11	1.69	.92 (−.51691, 2.3582)	.202
3 days post	15	−.08	1.72	20	−.17	2.10	.09 (−1.26056, 1.4472)	.889
10 days post	15	.39	1.54	18	.15	1.54	.24 (−.89177, 1.3722)	.667

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Table 3 Change in subjects' hours asleep from baseline by gender after completing five sessions.

Data from	Gender	Treated			Control			Mean difference (95% CI)	Sig 2-tailed
		n	Mean	SD	*n*	Mean	SD		
Day 2	Male	10	1.10	2.77	19	0.21	1.58	.89 (−0.76, 2.54)	.041
	Female	8	0.13	1.96	3	1.67	0.58	−1.54 (−4.22, 1.14)	
Day 3	Male	11	.55	2.38	19	.17	1.34	.38 (−1.03, 1.79)	.141
	Female	8	−.38	1.60	3	.67	1.53	−1.04 (−3.47, 1.38)	
Day 4	Male	11	.18	1.94	19	.16	1.30	.02 (−1.19, 1.23)	.520
	Female	8	1.13	.99	3	.00	1.00	1.13 (−.40, 2.65)	
Day 5	Male	10	1.80	2.53	18	.78	1.59	1.0 (−.57, 2.62)	.031
	Female	8	−.50	1.41	3	.67	.58	−1.17 (−3.12,.79)	
3 days post	Male	11	1.09	2.51	17	.53	1.70	.56 (−1.1, 2.19)	.278
	Female	8	.63	1.41	3	1.00	1.73	−.38 (−2.65, 1.90)	
10 days post	Male	11	.45	2.30	14	.86	1.41	−.40 (−1.94, 1.14)	.113
	Female	5	.80	.45	3	−1.67	4.04	2.47 (−1.8, 6.69)	

Discussion

The principle findings of this pilot study touch on the safety, tolerability, and efficacy of CES for the treatment of insomnia. As this study demonstrated, CES is safe with only minor side effects reported by the subjects. Only two subjects from the treatment group, both after a single session, withdrew from the study. In a similar manner, this study found CES well tolerated, particularly when viewed in terms of the number of subjects who completed the full five sessions. Over three-fourths of the enrolled study subjects completed the full five sessions, a testament to the subjects' quest for a good nights' sleep and the well-tolerated CES.

In terms of efficacy, the potential benefit of CES improving sleep was encouraging but not decisive. This study did hint at the possibility of CES increasing total time slept. The researchers identified a nearly significant increase in total time slept after three CES treatments among all study subjects. A closer examination of this group revealed an interesting gender bias, with men reporting a robust increase in total time slept of 53 min after one CES treatment, a decay in effect over the next two interventions, and then a 61 min improvement in total time slept after the fourth treatment.

The investigators recognize certain strengths and weaknesses in this study. Among the former, is the randomized, double blinded, sham controlled study design. The nearly even split between the control and treatment cohorts was another strength along with the mostly similar demographics between the two groups. Among the weaknesses, perhaps the main limitation is the sample size. A larger study group might identify more robust findings and at the same time possibly enroll more women.

There are very few modern rigorous studies examining CES and insomnia. As a consequence, this study occupies a fairly important niche. Based on the results of this pilot study, the investigators can propose certain mechanisms that would be worthy of future research. The inconsistent, but at times significant effect of CES on total time slept is an intriguing finding. One possible explanation for these results would focus on CES dosing. The researchers speculate that the up and down effect of CES on total time slept could be the result of an insufficient dose. Dosing for CES is the product of micro amperage, frequency, time per session, and number of sessions. The results from this study follow five daily, 60 min sessions conducted with 100 μA. This formula produced the inconsistent, but at two points, favorable improvement in total time slept among men.

It seems reasonable to speculate that increasing the micro amperage, adjusting the frequency, time per session, or number of sessions might result in an even greater improvement in sleep. From the clinical standpoint the best doing option would probably be an increase in the micro amperage or an adjustment in the frequency without a corresponding increase in the number or length of sessions. In any event, these unanswered questions might suggest that future research focus on identifying the most effective dosing formula.

At this point clinicians cannot claim CES is the Holy Grail for the non-pharmacologic treatment of chronic insomnia. Even so, the investigators do believe the present study lends support for further research. In the final analysis, the results of this study provide a sort of map which can guide future researchers towards that elusive goal.

Conflict of interest statement

The authors have no conflict of interest to report.

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References

1. Jindal RD, Buysse DJ, Thase ME. Maintenance treatment of insomnia: what can we learn from the depression literature? *American Journal of Psychiatry* 2004;**161**(1):19–24.
2. Johnson EO, Roehrs T, Roth T, Breslau N. Epidemiology of alcohol and medication as aids to sleep in early adulthood. *Sleep* 1998;**21**(2):178–86.
3. Walsh JK, Schweitzer PK. Ten-year trends in the pharmacological treatment of insomnia. *Sleep* 1999;**22**(3):371–5.
4. Moloney ME, Konrad TR, Zimmer CR. The medicalization of sleeplessness: a public health concern. *American Journal of Public Health* 2011;**101**(8):1429–33.
5. Krakow B, Ulibarri VA, Romero E. Persistent insomnia in chronic hypnotic users presenting to a sleep medical center: a retrospective chart review of 137 consecutive patients. *Journal of Nervous and Mental Disease* 2010;**198**(10):734–41.
6. Brower KJ, McCammon RJ, Wojnar M, Ilgen MA, Wojnar J, Valenstein M. Prescription sleeping pills, insomnia, and suicidality in the National Comorbidity Survey Replication. *Journal of Clinical Psychiatry* 2011;**72**(4):515–21.
7. Troxel WM, Kupfer DJ, Reynolds 3rd CF, Frank E, Thase ME, Miewald JM, et al. Insomnia and objectively measured sleep disturbances predict treatment outcome in depressed patients treated with psychotherapy or psychotherapy-pharmacotherapy combinations. *J Clin Psychiatry* 2012;**73**(4):478–85.
8. Bryant RA, Creamer M, O'Donnell M, Silove D, McFarlane AC. Sleep disturbance immediately prior to trauma predicts subsequent psychiatric disorder. *Sleep* 2010;**33**(1):69–74.
9. McCall WV, Blocker JN, D'Agostino Jr R, Kimball J, Boggs N, Lasater B, et al. Insomnia severity is an indicator of suicidal ideation during a depression clinical trial. *Sleep Medicine* 2010;**11**(9):822–7.
10. Krakow B, Ribeiro JD, Ulibarri VA, Krakow J, Joiner Jr TE. Sleep disturbances and suicidal ideation in sleep medical center patients. *Journal of Affective Disorders* 2011;**131**(1–3):422–7.
11. Budhiraja R, Roth T, Hudgel DW, Budhiraja P, Drake CL. Prevalence and polysomnographic correlates of insomnia comorbid with medical disorders. *Sleep* 2011;**34**(7):859–67.
12. Lande RG, Gragnani C. Nonpharmacologic approaches to the management of insomnia. *Journal of the American Osteopathic Association* 2010;**110**(12):695–701.
13. Morin CM, Benca R. Chronic insomnia. *Lancet* 2012;**379**(9821):1129–41.
14. Sarris J, Byrne GJ. A systematic review of insomnia and complementary medicine. *Sleep Medicine Reviews* 2011;**15**(2):99–106.
15. Jarzembski WB. Electrical stimulation and substance abuse treatment. *Neurobehavioral Toxicology and Teratology* 1985;**7**(2):119–23.
16. Feighner JP, Brown SL, Olivier JE. Electrosleep therapy. A controlled double blind study. *Journal of Nervous and Mental Disease* 1973;**157**(2):121–8.
17. Weiss MF. The treatment of insomnia through the use of electrosleep: an EEG study. *Journal of Nervous and Mental Disease* 1973;**157**(2):108–20.
18. Frankel BL, Buchbinder R, Snyder F. Ineffectiveness of electrosleep in chronic primary insomnia. *Archives of General Psychiatry* 1973;**29**(4):563–8.
19. Cartwright RD, Weiss MF. The effects of electrosleep on insomnia revisited. *Journal of Nervous and Mental Disease* 1975;**161**(2):134–7.
20. Klawansky S, Yeung A, Berkey C, Shah N, Phan H, Chalmers TC. Meta-analysis of randomized controlled trials of cranial electrostimulation. Efficacy in treating selected psychological and physiological conditions. *Journal of Nervous and Mental Disease* 1995;**183**(7):478–84.
21. McCrory DC. Cranial electrostimulation for headache: meta-analysis. *Journal of Nervous and Mental Disease* 1997;**185**(12):766–7.
22. Gunther M, Phillips KD. Cranial electrotherapy stimulation for the treatment of depression. *Journal of Psychosocial Nursing and Mental Health Services* 2010;**48**(11):37–42.
23. Rosa MA, Lisanby SH. Somatic treatments for mood disorders. *Neuropsychopharmacology* 2012;**37**(1):102–16.
24. Rose KM, Taylor AG, Bourguignon C. Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms, and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease. *Applied Nursing Research* 2009;**22**(2):119–25.
25. The Alpha-Stim SCS. Available from: http://www.biof.com/onlinestore/alpha/SCS.asp [accessed 18.11.12].
26. Feusner JD, Madsen S, Moody TD, Bohon C, Hembacher E, Bookheimer SY, et al. Effects of cranial electrotherapy stimulation on resting state brain activity. *Brain Behaviour* 2012;**2**(3):211–20.
27. Schroeder MJ, Barr RE. Quantitative analysis of the electroencephalogram during cranial electrotherapy stimulation. *Clinical Neurophysiology* 2001;**112**(11):2075–83.
28. Kennerly R. QEEG analysis of cranial electrotherapy: a pilot study. *Journal of Neurotherapy* 2004;**8**:112.
29. Moul DE, Pilkonis PA, Miewald JM, Carey TJ, Buysse DJ. Preliminary study of the test–etest reliability and concurrent validities of the Pittsburgh Insomnia Rating Scale (PIRS). *Sleep* 2002;**25**(Abstract Supplement):A246–7.

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