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Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms, and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease☆

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Abstract

Purpose: The purpose of this work was to investigate the effects of cranial electrical stimulation (CES) on sleep disturbances, depressive symptoms, and caregiving appraisal.
Methods: Thirty-eight participants were randomly assigned to receive active CES or sham CES for 4 weeks.
Results: Both intervention groups demonstrated improvement in study measures from baseline scores. A trend toward statistically significant differences in daily sleep disturbances was found between the groups. No differences in depressive symptoms and caregiving appraisal were found between the groups.
Conclusions: These findings did not fully support the efficacy of the short-term use of active CES versus sham CES to improve sleep disturbances, depressive symptoms, or caregiving appraisal.

1. Background

Family caregivers are the mainstay of caregiving support to persons with Alzheimer's disease (AD). More than 30% of caregivers for older people are, themselves, aged ≥ 65 years (U.S. Department of Health and Human Services, 2001). The physical and psychological consequences of providing care to a person with AD may be detrimental to the caregiver, particularly if the caregiver is elderly, has a negative appraisal of one's caregiving situation, and is the spouse of the care recipient. The negative health outcomes for caregivers, compared to those for noncaregiving persons matched for age, include higher rates of sleep disturbances and depressive symptoms, poorer self-ratings of overall health status, and a 63% higher mortality rate (McCurry, Logsdon, Vitiello, & Teri, 1998; Schulz & Beach, 1999).

Sleep disturbances, depressive symptoms, and negative appraisal of a caregiving situation pose threats to elderly caregivers of persons with AD in terms of the caregivers' own physical and psychological well-being and their ability to provide adequate care to the care recipient. Although pharmacological therapies are most often used to relieve sleep disturbances and depressive symptoms, these medications often have poorly tolerated side effects on older people. For many elderly persons, hypnotic medications prescribed to relieve sleep disturbances may, in fact, pose serious threats to their own safety and to the safety of those who are in their care. Thus, nonpharmacological interventions, such as cranial electrical stimulation (CES), may offer viable alternatives to ameliorating sleep disturbances and depressive symptoms in caregivers, while reducing the side effects encountered with conventional pharmacological regimens.

CES involves the use of a small battery-operated device that delivers low levels of alternating electrical current to the head via clips attached to the earlobes (Kirsch, 2002). CES therapy has had positive effects on the treatment of sleep disturbances, depressive symptoms, perceived stress, and other disorders in a variety of patient populations, including

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persons with fibromyalgia, depressive symptoms, anxiety, and insomnia (Tyers & Smith, 2001a, 2001b). Although the precise mechanism of action of CES in unknown, it is believed that CES stimulates the vagus nerve, causing parasympathetic response and resultant relaxation. Additionally, increases in blood and cerebrospinal fluid levels of specific neurotransmitters, including serotonin, norepinephrine, dopamine, and β-endorphin, have been reported when CES was used for both 1 and 2 weeks (Shealey et al., 1998). However, no studies to date have specifically tested the efficacy of CES in either an elderly population or a caregiver population. Therefore, the purpose of this study was to investigate the short-term use of the *AlphaStim* CES device in sleep disturbances, depressive symptoms, and subjective appraisal in elderly persons who are the primary caregivers for their spouses with AD.

1.1. Framework

Psychoneuroimmunology (PNI) serves as the framework for this study. PNI focuses on the influence of thoughts on behavior; on interactions between the central nervous system, the endocrine system, and the immune system; and on the subsequent impact of these interrelationships on overall health. The PNI framework provides a model depicting the potential influence of the negative appraisal of the stressor (caregiving) on the development of sleep disturbances and depressive symptoms, and how these symptoms, in turn, may contribute to the development of other disease states stemming from neuroendocrine and immunologic dysregulation (Irwin, 2002; McEwen, 2002).

The concurrent development of depressive symptoms and sleep disturbances is thought to occur as a result of the dysregulation of the hypothalamic–pituitary–adrenalcorticoid (HPA) and sympathetic–adrenal–medullary (SAM) axes in chronic stressful situations such as caregiving. Long-term activation of the HPA and SAM axes leads to dysregulation of neurotransmitters and neurotransmitter receptors. The levels and functions of neurotransmitters such as serotonin, norepinephrine, and dopamine have been shown to be affected by HPA and SAM axes dysregulation, with resultant disturbances in sleep and mood.

2. Methods

2.1. Design

This study was a randomized, double-blind, controlled pilot study that used repeated measures throughout the 4-week intervention. Study participants were randomly assigned to one of two groups: active *AlphaStim* CES or sham CES. The study protocol was approved by the Institutional Review Board at the University of Virginia. Written informed consent was obtained from all participants.

Power analysis was performed based on the variable of sleep disturbance as measured by the Pittsburgh Sleep Quality Index (PSQI) using nQuery power analysis software. The means and standard deviations from a study on the effects of nonpharmacological intervention on sleep disturbances in elderly caregivers of persons with AD (McCurry et al., 1998) were used to conduct power analysis for the proposed study. Given the means and standard deviations from the McCurry et al. study, a sample size of 38 (19 per group) would yield 80% power to detect differences between active and sham intervention groups over time in this research.

2.2. Sample

Participants were recruited from primary care providers and caregiver support groups in a rural setting in the northeastern United States. Forty-four participants provided informed consent to participate in the study. Inclusion criteria were as follows: (1) primary caregiver for a spouse with AD or multi-infarct dementia in the home environment; (2) age of $\geq$ 60 years; (3) cognitive ability to complete questionnaires; (4) a Geriatric Depression Scale (GDS) score of $\geq$ 10 indicating the presence of depressive symptoms (Yesavage et al., 1983); and (5) willingness to wear the *AlphaStim* device for 60 minutes/day in the course of 4 weeks. Potential participants were excluded if they were using an antidepressant medication or a botanical agent with antidepressant properties (e.g., *Ginkgo biloba*, St. John's wort), or if they had an implantable device, such as a pacemaker or an internal defibrillator. After screening, 39 of 44 persons were found to be eligible based on the inclusion and exclusion criteria. Of the five individuals excluded from participation, two persons were taking antidepressant medications and three persons scored <10 on the GDS, indicating no depressive symptoms. Thirty-eight of the 39 eligible participants completed the trial (active CES group, n = 19; sham CES group, n = 19). One person withdrew from the study after completing baseline measures, but prior to beginning CES intervention, due to health concerns related to recent hospitalization.

Participants' and care recipients' demographic data are presented in Table 1. The intervention groups did not differ in any demographic variable except age (t = −2.081, p < .05), with the caregivers in the sham CES group being older (76.2 years; SD = 5.60) than those in the active CES group (71.9 years; SD = 7.78). There was >95% adherence to the study protocol by participants in both intervention groups, as documented by the participants' completion of a daily log of CES use.

2.3. CES intervention

The CES device used in this study was the *Alpha-Stim* Cranial Electrotherapy Stimulator device (Electromedical Products International, Mineral Wells, TX). This battery-operated device is relatively small and compact (3.9 in. long, 3 in. wide, and 0.9 in. thick). A single cable attaches the device to two ear clips worn by the participant. The device was preset at an electrical stimulation intensity of 100 μA; the

Table 1
Demographic characteristics of the study sample

	Active CES (n = 19)	Sham CES (n = 19)	Statistics	p
Caregivers				
Age (years) [M (SD)]	71.94 (7.78)	76.52 (5.60)	−2.081 [a]	.045
Gender [n (%)]				
Female	14 (73.7)	11 (57.9)	1.052 [b]	.305
Male	5 (26.3)	8 (42.1)		
Education (years) [M (SD)]	15.26 (2.92)	14.47 (3.38)	0.667 [a]	.509
Length of time in caregiving role (months) [M (SD)]	58.63 (50.75)	57.31 (42.12)	0.087 [a]	.931
Average hours of care provided by caregiver (weekly) [M (SD)]	126.21 (60.50)	147.28 (43.01)	−1.238 [a]	.224
Perception of financial burden [n (%)]				
Yes	5 (26.3)	6 (31.6)	0.128 [b]	.721
No	14 (73.7)	13 (68.4)		
Care recipients				
Age (years) [M (SD)]	73.89 (8.24)	78.26 (6.13)	−1.853 [a]	.072
Length of time of memory changes (months) [M (SD)]	66.00 (53.17)	62.89 (40.16)	0.203 [a]	.840
Diagnosis (n)				
AD	16	13	3.310 [b]	.191
Multi-infarct dementia	1	5		
Unknown	2	1		
Global Deterioration Scale score (cognitive decline)				
3 (mild)	0	1	6.218 [b]	.183
4 (moderate)	7	4		
5 (moderately severe)	6	6		
6 (severe)	6	4		
7 (very severe)	0	4		

[a] t test.
[b] Chi-square test.

timer was preset at 60 minutes; and the pulse rate was preset at 0.05 pulse/second, as recommended by the manufacturer. These preset parameters have been shown to attain the appropriate waveform configuration to achieve physiological changes in neurotransmitters. An electrical stimulation of 100 μA is generally an imperceptible amount of electrical current to most persons; this is important as this setting permitted the blinding of the study participants. The sham device was identical in appearance to the active device, with the only difference being that no electrical current was delivered.

2.4. CES protocol

The primary investigator gave both verbal and written instructions on the proper use of the *AlphaStim* CES device. Participants in both intervention groups (active and sham) received a device at the time of randomization and were given a demonstration of the use of the device. Participants also gave a return demonstration of the use of the *AlphaStim* device to ensure that they understood its use. Participants were instructed to wear the CES device for 60 minutes/day for the 4-week intervention period and to complete a daily log of CES usage. Study outcome measures were obtained at baseline and on Weeks 2 and 4.

2.5. Outcome measures

The PSQI (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) was used to measure self-reported sleep disturbances experienced by the caregivers during the past month. The component scores yield a global score in a range of 0–21 points, where 0 = *no difficulty* and 21 = *severe difficulties in all areas*. A cutoff score of ≥ 5 identifies persons with poor sleep. Test–retest reliability, as well as a sensitivity of 89.6% and a specificity of 86.5%, has been established for this scale. Scores on the PSQI were also analyzed with a three-factor scoring model proposed by Cole et al. (2006).

The General Sleep Disturbance Scale (GSDS) was used to measure caregivers' reports of sleep disturbances at baseline and at 2 and 4 weeks. The GSDS is a 21-item questionnaire that rates aspects of sleep quality and quantity during the past week (Lee, Portillo, & Miramontes, 1998). This instrument uses an 8-point frequency scale, with responses ranging from 0 = *never* to 7 = *every day*. Higher scores indicate more sleep disturbances. A mean total GSDS score, or any mean on the three subscales (sleep quality, daytime function, and sleep medication), of ≥3 is equivalent to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria for insomnia or sleeping difficulty. The GSDS has established internal consistency and reliability, with Cronbach's alpha values ranging from .80 to .88 (Lee et al., 1998). Participants also responded to a set of sleep diary questions pertaining to the previous night's sleep, including the time the participant went to bed, the time taken to fall asleep (sleep onset latency; in minutes), the number of nighttime awakenings, and the time the participant got out of bed in the morning for the day.

Depressive symptoms in the study participants were measured using the GDS at baseline and at 2 and 4 weeks. Total scores range from 0 to 30, with 0–9 = *no depressive symptoms*; 10–19 = *mild depressive symptoms*; and 20–30 = *severe depressive symptoms* (Yesavage et al., 1983). The Cronbach's alpha for the scale was reported as .95, a with test–retest reliability of 0.85 (Yesavage et al., 1983).

Caregiving appraisal in the study participants was measured using the Philadelphia Geriatric Center Caregiving Appraisal Scales (PGCCAS) (Lawton, Kleban, Moss, Rovine, & Glicksman, 1989). The PGCCAS, specifically designed to measure the impact of caring for disabled older people by family caregivers, comprises 28 questions representing 4 subscales (burden, satisfaction, mastery, and impact). The Cronbach's alpha for the entire scale was reported as .92 in a sample of community-dwelling spouse caregivers of persons with dementia (DiBartolo & Soeken, 2003). Test–retest reliability ranged between .75 and .78 in 103 caregivers of institutionalized demented persons (Lawton et al., 1989). For this study, the researcher analyzed each of the four subscales of the PGCCAS.

2.6. Data analysis

The Statistical Package for the Social Sciences, version 12.0 (SPSS, Chicago, IL), was used to enter, clean, and verify the data. Because this research was an exploratory study, the level of significance was set at .05 for all tests, and trends were explored.

Descriptive statistics were calculated for all demographic and study variables. Differences in the demographic characteristics of the intervention groups were compared using chi-square analysis for categorical variables and using independent *t* tests for continuous variables. Baseline differences in study outcome measures of interest (scores on the PSQI, GSDS, GDS, and PGCCAS) between the two intervention groups were examined using independent *t* tests.

Comparative analyses of the outcome variables of sleep disturbances, depressive symptoms, and subjective appraisal in the 4-week trial period were conducted via one-way analysis of covariance (ANCOVA) models for sleep outcomes using the PSQI, or via repeated measures ANCOVA models for all other analyses. The between-subjects factor was treatment group, with two levels (active CES and sham CES), and the within-subjects factor was time, with two levels (Weeks 2 and 4). Baseline scores of dependent variables (sleep disturbances, depressive symptoms, and subjective appraisal) were used as covariates in these analyses.

3. Results

Study outcome findings at the end of the 4-week intervention period are presented in Table 2.

Table 2
Mean scores on study outcomes between intervention groups at the end of the study (Week 4)

	Active CES	Sham CES	*p*
Sleep quality (PSQI) [a]	7.80	8.24	.68
Sleep efficiency (PSQI) [a]	2.39	2.6	.74
Daily disturbances (PSQI) [a]	2.34	2.65	.09 [b]
Sleep disturbances (GSDS) [c]	2.12	2.20	.37
Sleep onset latency (minutes; sleep diary) [c]	27.42	33.42	.27
Depressive symptoms (GDS) [c]	9.06	9.45	.24
Caregiving burden (PGCCAS) [c]	36.77	38.75	.66
Caregiving impact (PGCCAS) [c]	22.26	23.10	.59
Caregiving satisfaction (PGCCAS) [c]	11.39	13.36	.11
Caregiving mastery (PGCCAS) [c]	20.39	21.54	.79

[a] One-way ANCOVA.
[b] Trend toward statistical significance.
[c] Repeated measures ANCOVA.

3.1. Sleep disturbances

There were no significant differences in overall scores on sleep disturbances or sleep quality between the intervention groups over time. A trend toward statistical significance (p = .09) in the daily disturbances subscale of the PSQI was found between the intervention groups, with participants in the active CES intervention group reporting a greater decrease in mean scores than those participants in the sham CES group. No statistically significant results in sleep onset latency were found between the two groups at baseline (p = .727) and at 4 weeks (p = .274), although clinically important differences were found. The active CES group reported a 9-minute decrease in sleep onset latency as compared to a 1-minute increase reported by participants in the sham CES group at the end of the 4-week study period.

3.2. Depressive symptoms

There were no significant differences in reports of depressive symptoms between the intervention groups over time (F = 9.022, p = .224). Participants in both intervention groups did show a decrease in reports of depressive symptoms in the 4-week study period, with final depressive scores in both groups falling below baseline scores.

3.3. Caregiving appraisal

No significant differences in the appraisal of caregiving situation were seen between the intervention groups over time, as indicated by scores on the four subscales of burden, mastery, impact, or satisfaction with caregiving situation.

4. Discussion

4.1. Comparison to other studies

4.1.1. Sleep disturbances

Prior studies have provided evidence that use of the *AlphaStim* CES device at identical settings in 3 weeks improved subjective reports of sleep in persons with

fibromyalgia (Lichtbroun, Raicer, & Smith, 2001; Tyers & Smith, 2001a, 2001b). In these studies, sleep was measured with a three-choice ordinal self-rating of quality of sleep, with response options of *little or no sleep*, *moderate sleep*, or *good very restful sleep*. These studies also demonstrated reduction in pain and tender points, which are classic symptoms of fibromyalgia. Thus, it is plausible that the reduction in pain and tender points found in these studies may have influenced the participants' reports of quality of sleep. These studies also reported improvement in fatigue as measured by the Profile of Mood States (POMS). Other studies of sleep disorders in persons with fibromyalgia have found that increased pain sensitivity and reports of fatigue in persons with this disorder are associated with increases in sleep disturbances.

Reports of sleep disturbances related to fatigue and daytime sleepiness are consistent with documented changes in sleep structure in older people. In this study, slight trends toward statistically significant differences in participants' reports of daily disturbances were found, whereas global scores of sleep quality did not show these differences. These findings suggest that the CES intervention may have been affecting other related indicators of sleep, such as fatigue and daytime sleepiness, that were not directly measured. The addition of instruments to measure related indicators of sleep, such as fatigue and daytime sleepiness, would strengthen the design of future studies of CES in older people.

4.1.2. Depressive symptoms

In this study, mean baseline scores on the GDS were minimal in both groups (12.84 in the active group and 13.10 in the sham group). Although these scores are consistent with the presence of mild depressive symptoms, the internal consistency of the GDS in this study was low (Cronbach's $\alpha = .340$). In further support of this low coefficient score, numerous participants verbalized having difficulty completing the GDS because of the format and the wording of some of the scale items. For example, several participants expressed turmoil with completing Item 10 ("Do you often feel helpless?"), Item 18 ("Do you frequently worry about the past?"), and Item 19 ("Do you find life very exciting?") on the GDS. Participants stated that the adverbs in these items (often, frequently, and very) and in other items made these items confusing for them and that they were not confident in their responses. Because obtaining a minimal score of 10 on the GDS was required for inclusion into the study, it is possible that some of the participants who did not truly exhibit depressive symptoms were enrolled into the study.

4.1.3. Caregiving appraisal

No prior published studies of CES and its effect on caregiving appraisal were identified. There are, however, studies of CES and its effects on perceptions of stress—a concept that is conceptually close to that of caregiving appraisal. Two of these studies used the *AlphaStim* device, with settings identical to the settings used in this study (Lichtbroun et al., 2001; Tyers & Smith, 2001a, 2001b). In these studies of adults with fibromyalgia, stress was measured using the POMS instrument. POMS provides subscale scores for anxiety, depression, anger, vigor, fatigue, and cognitive function, and a total mood disturbance score (Educational and Industrial Testing Service, San Diego, CA). In all three studies, positive results for stress alleviation were achieved in the active CES groups, whereas these measures of stress showed mixed results in persons in the sham CES group.

The results of this current pilot study do not support the results of CES on the reduction of stress or caregiving appraisal found in other studies. However, the concepts measured by the PGCCAS may be different in nature from those measured in the aforementioned studies that used POMS as a measure of stress. Thus, it is difficult to make comparisons between the studies.

4.2. Strengths of the study

Enrolling only spousal caregivers of persons with AD is a strength of this study. The literature supports the view that spousal caregivers experience the caregiving situation differently than do persons in other familial roles who are caregivers (Ory, Yee, Tennstedt, & Schulz, 2000). Studies report that spousal caregivers exhibit more depressive symptoms and have other coping difficulties compared to other family members who are engaged in the caregiving role. By limiting enrollment exclusively to spousal caregivers, the effects of the intervention were not confounded by the caregiver's familial role in relation to the care recipient.

Lengthy study protocols for intervention studies have been identified as a reason for the high attrition rates of caregivers. The length of time for this study protocol was 4 weeks, as this amount of time has shown beneficial results in studies using CES. In this study, the attrition rate was low, with only one caregiver dropping out from the study prior to the 4-week study conclusion time. Participants in this study were able to complete all aspects of the study protocol in their home environments. This is a particular strength of the study protocol as this feature permitted participants to continue with their daily home routines without the need for contracting for respite care provisions for the care recipients. Numerous study participants verbalized that the ability to stay in their homes and the absence of a need to travel to participate in this study were strong incentives for their participation in the study. The study participants demonstrated a >95% adherence rate with the study protocol, lending further support to the ease of use of the CES device.

4.3. Limitations of the study

Several limitations of this study relate to design. First, there were only subjective measurements of sleep outcomes used in the study. There is ongoing research regarding correlations between subjective and objective measurements of sleep. It has been repeatedly demonstrated that "non-complaining" older men and women manifest significantly

disturbed sleep. It is suggested that healthy "noncomplaining" older adults appear to adapt their perceptions of what is "acceptable" sleep and, therefore, do not necessarily complain (Vitiello, Larsen, & Moe, 2004). In this study, 74% of the study participants rated their baseline overall health as *excellent* or *very good*, and reported minimal, if any, sleep disturbances at baseline. Thus, it is possible that although subjective measurements of sleep did not reveal sleep disturbances in this sample, objective measurements may have revealed these difficulties. In future studies, an objective measurement of sleep, in addition to subjective measures and sleep-related outcomes (e.g., fatigue and daytime sleepiness), should be used.

The small study sample did not allow for adequate power for study outcome measures. The power analysis for this study was based upon the results of a previous study (McCurry et al., 1998) in which higher scores on the PSQI were obtained at baseline, with subsequent higher variability in scores than were found in this current study. In future studies of CES in caregiving populations, the results from this current study should be used to perform a more precise power analysis.

Additionally, the study design did not control for any effects the study participants may have experienced from their interactions with the study coordinator or from the use of a device as intervention in this study. Participants in both intervention groups received weekly telephone calls from the investigator regarding study-related issues (adherence to protocol, change in medications). Although most of these telephone calls were brief (<5 minutes), several participants' telephone calls lasted >10 minutes. One participant, who was randomized to the sham group, was blind and, consequently, was unable to change the battery in his device every week. For this participant, the investigator made weekly visits to his residence to change the device battery. During these weekly visits, it was not uncommon for the participant and his care recipient to invite the investigator to eat snacks or to engage in conversation beyond the purpose of battery change. Thus, it is plausible that this participant, specifically, and all participants, in general, perceived a supportive interaction between themselves and the investigator and that this interaction improved their ratings of depressive symptoms and caregiving appraisal. Additionally, investigations using medical devices, such as the CES device used in this study, are proposed to have high "placebo effects" (Kaptchuk, Goldman, Stone, & Stason, 2000).

Participants in both intervention groups anecdotally reported "taking more time for themselves" as a result of being participants in this study. Although this study was not designed to obtain qualitative measures of study outcomes, numerous study participants made remarks to the investigator that on the hour each day during which they had used the CES device, they had, concurrently, chosen to read a book or to relax at home. Although the study protocol did not mandate that the participants be sedentary during their daily use of the CES device, many participants reported that they were inactive during this time. Consistent with the literature regarding the health effects of high adherence to treatment, whether active or placebo, the participants in both groups may have reported improvements in sleep disturbances, depressive symptoms, and caregiving appraisal as a result of the perception of actively working to improve these study outcomes (Granger et al., 2005). This explanation is plausible, as participants in this study reported a 95% adherence rate to the daily use of the CES device.

5. Conclusions

This study was a randomized, double-blind, clinical trial exploring whether short-term use of CES improved sleep disturbances, depressive symptoms, and caregiving appraisal in elderly caregivers to spouses with AD. A trend toward statistically significant differences in reports of daily disturbances of sleep was found, with participants in the active CES group demonstrating improvement in this area. Clinically meaningful decreases in sleep latency were found in the active CES group, with a reduction of 9 minutes in the active group as compared to an increase of 1 minute in the sham group. Depressive symptoms in both intervention groups decreased to levels that indicated the absence of depressive symptoms. However, these changes were not statistically significant. The limitations of the study may have obscured any effects of CES that may have been prevalent. Thus, a larger sample size, a more precise power analysis based upon the results of this study, a longer intervention period of CES, the addition of an attention-control group, measurement of other indices of sleep (daytime sleepiness, fatigue), and objective measures of sleep disturbances should be used in future studies of CES in elderly caregivers.

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