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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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Background

Family caregivers are the mainstay of caregiving support to persons with Alzheimer's disease (AD). Over 30 percent of caregivers for the elderly are, themselves, age 65 years or older (U.S. Dept. 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 his or her caregiving situation, and is the spouse of the care recipient. The negative health outcomes for caregivers as compared to non-caregiving persons matched on 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 & Beech, 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 caregiver's own physical and psychological wellbeing, and in the ability they have to provide adequate care to the care recipient. Although pharmacologic therapies are most often used to relieve sleep disturbances and depressive symptoms, these medications often have poorly tolerated side effects in the elderly. For many elderly persons, the 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, non-pharmacologic interventions, such as cranial electrical stimulation, may offer viable alternatives to ameliorating sleep disturbances and depressive symptoms in caregivers, while reducing the side effects encountered by conventional pharmacologic medicines.

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Cranial electrical stimulation (CES) involves the use of a small, battery-operated device that delivers low levels of alternating electrical current to the head via clips that are 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 persons with fibromyalgia, depressive symptoms, anxiety, and insomnia (Tyers & Smith, 2001). Although the precise mechanism of action of CES is unknown, it is believed that CES may stimulate the vagus nerve, causing a 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 one and two weeks (Shealey et al., 1998). However, no studies to date have specifically tested the efficacy of CES in either an elderly or a caregiver population. Therefore, the purpose of this study was to investigate the short-term use of the *AlphaStim*® CES device on sleep disturbance, depressive symptoms, and subjective appraisal in elderly persons who are the primary caregivers for their spouses with AD.

Framework

Psychoneuroimmunology (PNI) serves as the framework for this study. PNI focuses on the influence of thoughts on behavior, and the interactions between the central nervous system (CNS), the endocrine system, and the immune system, and the subsequent impact of these interrelationships on overall health. The PNI framework provides a model depicting the potential influence of 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-adrenocortical (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 the dysregulation of neurotransmitters and neurotransmitter receptors. Levels and function 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 in mood.

Methods

Design

This study was a randomized, double-blind, controlled pilot study that used repeated measures throughout the four-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.

A power analysis was calculated based on the variable of sleep disturbances as measured by the Pittsburgh Sleep Quality Index (PSQI) using nQuery® power analysis software. Means and standard deviations from a study on the effects of a non-pharmacologic intervention on sleep disturbances in elderly caregivers of persons with AD (McCurry et al., 1998) were used to conduct the 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.

Sample

Participants were recruited from primary care providers and from caregiver support groups in a rural setting in the northeastern United States. A total of 44 participants provided informed consent to participate in the study. Inclusion criteria were: (1) primary caregiver for a spouse with Alzheimer's disease or multi-infarct dementia in the home environment; (2) age 60 years or greater; (3) cognitive ability to complete questionnaires; (4) Geriatric Depression Scale score of 10 or greater indicating the presence of depressive symptoms (Yesavage, Brink, Rose, Lum, et al., 1983); and (5) willingness to wear the *AlphaStim*® device for 60 minutes per day over the course of 4 weeks. Potential participants were excluded if they were using an antidepressant medication or a botanical 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 the 44 persons were eligible according to the inclusion and exclusion criteria. Of the five individuals excluded from participation, two persons were taking antidepressant medications and three persons scored below 10 on the Geriatric Depression Scale, indicating no depressive symptoms. Thirty-eight of the eligible 39 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 the CES intervention, due to health concerns related to a recent hospitalization.

Participant and care recipient demographic data are presented in Table 1. The intervention groups did not differ on 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). Adherence to the study protocol was over 95% by participants in both intervention groups as documented by participants' completion of a daily log of CES use.

Cranial Electrical Stimulation Intervention

The CES device used in this study was the *Alpha-Stim*® Cranial Electrotherapy Stimulator device (Electromedical Products International, Inc., Mineral Wells, Texas). (Insert picture of device about here). This battery-operated device is relatively small and compact (3.9 inches long, 3 inches wide, and 0.9 inches thick). A single cable attaches the device to two ear clips worn by the participant. The device was preset at an intensity level of electrical stimulation 100 microamps; the timer was preset at 60 minutes; and the pulse rate at .05 pulses-per-second (pps), as recommended by the manufacturer. These preset parameters have been shown to attain the appropriate waveform configuration to achieve physiological changes in neurotransmitters. Electrical stimulation of 100 microamps 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.

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 each day for the 4-week intervention period and to complete a daily log of CES usage. Study outcome measures were obtained at baseline and at weeks 2 and 4.

Outcome Measures

The Pittsburgh Sleep Quality Index (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, with a range of 0–21 points. A global score of “0” indicates no difficulty and a “21” indicates severe difficulties in all areas. A cutoff score of 5 or greater identifies persons with poor sleep. Test-retest reliability has been established for this scale as well as sensitivity of 89.6% and specificity of 86.5. Scores on the PSQI were also analyzed with a three-factor scoring model as 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 et al., 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 three or greater is equivalent to the DSM-IV criteria for insomnia or sleeping difficulty. The GSDS has established internal consistency and reliability with Cronbach’s alpha ranging from .80–.88 (Lee, 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, time taken to fall asleep (sleep onset latency, in minutes), number of nighttime awakenings, and the time the participant got out of bed in the morning for the day.

Depressive symptoms were measured in study participants using the Geriatric Depression Scale at baseline and at 2 and 4 weeks. Total scores range from 0 to 30, with scores between 0 and 9 indicating no depressive symptoms; 10–19 indicating mild depressive symptoms; and 20–30 indicating severe depressive symptoms (Yesavage, Brink, Rose, Lum, Huang, Adey, et al., 1983). Cronbach’s alpha for the scale was reported as 0.95; with test-retest reliability of 0.85 (Yesavage et al, 1983).

Caregiving appraisal was measured in study participants using the Philadelphia Geriatric Center Caregiving Appraisal Scales (PGCCAS) (Lawton, Kleban, Moss, Rovine, et al., 1989). The PGCCAS scale, specifically designed to measure the impact of caring for disabled older people by family caregivers, is comprised of 28 questions, representing the four subscales of burden, satisfaction, mastery, and impact. 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–.78 on 103 caregivers of institutionalized demented persons (Lawton et al, 1989). For this study, the researcher analyzed each of the four subscales of the PGCCAS.

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 0.05 for all tests, and trends were explored.

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

Comparative analysis of the outcome variables of sleep disturbances, depressive symptoms, and subjective appraisal over the 4-week trial period were conducted via one-way analysis of covariance models (ANCOVA), for sleep outcomes using the PSQI or repeated measures

ANCOVA models for all other analyses. The between-subjects factor was treatment group, with two levels (active CES, sham CES) and the within-subjects factor was time, with two levels (weeks 2 and 4). Baseline scores of the dependent variables (sleep disturbances, depressive symptoms, and subjective appraisal) were used as covariates in these analyses.

Results

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

Sleep Disturbances

There were no significant differences between the intervention groups over time in overall scores regarding sleep disturbances or sleep quality. A trend toward statistical significance ($p=.09$) was found between intervention groups on the daily disturbances subscale of the PSQI, 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 were found in sleep onset latency 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.

Depressive Symptoms

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

Caregiving Appraisal

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

Discussion

Comparison to Other Studies

Sleep disturbances—Prior studies provided evidence that use of the *AlphaStim*® CES device using identical settings over three weeks improved subjective reports of sleep in persons with fibromyalgia (Lichtbroun et al., 2001; Tyers & Smith, 2001). In these studies, sleep was measured with a 3-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 a reduction in pain and tender points in the participants, classical symptoms of fibromyalgia. Thus, it is plausible that the reductions in pain and tender points found in these studies may have influenced the participant's reports of quality of sleep. These studies also reported improvement in fatigue as measured by the Profile of Mood States. 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 the documented changes in sleep structure in the elderly. In this study, slight trends toward statistically significant differences in participants' reports of daily disturbances were found, while 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 the elderly.

Depressive symptoms—In the current study, mean baseline scores on the Geriatric Depression Scale (GDS) were minimal in both groups (12.84 in the active group and 13.10 in the sham group). While 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 over completing item numbers 10 (*"Do you often feel helpless?"*), 18 (*"Do you frequently worry about the past?"*), and 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 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 were enrolled into the study who did not truly exhibit depressive symptoms.

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 those settings used in this study (Lichtbroun et al., 2001; Tyers & Smith). In these studies of adults with fibromyalgia, stress was measured using the Profile of Mood States (POMS) instrument. The POMS provides subscale scores for anxiety, depression, anger, vigor, fatigue, cognitive function, and a total mood disturbance score (Educational and Industrial Testing Service, San Diego, CA). In all three studies, positive results were achieved in the alleviation of stress in the active CES groups, while these measures of stress showed mixed results in persons in the sham CES groups.

The results of this current pilot study do not support the results of CES on the reduction of stress, or caregiving appraisal that have been 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 the POMS as a measure of stress. Thus, it is difficult to make comparisons between the studies.

Strengths of the Study

Enrolling only spousal caregivers of persons with AD is a strength of this study. 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 than do 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 high attrition rates of caregivers. The length of time for the current 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 in 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 not have to travel to participate in this

study was a strong incentive for their participation in the study. Study participants demonstrated over a 95% adherence rate with the study protocol, lending further support to the ease of use of the CES device.

Limitations of the Study

Several limitations to this study relate to the design. First, there were only subjective measurements of sleep outcomes used in the study. Research is ongoing regarding the correlations between subjective and objective measurements of sleep. It has been repeatedly demonstrated that “noncomplaining” 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, et al., 2004). In this study, 74% of 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 should be used in addition to subjective measures and sleep-related outcomes (e.g., fatigue and daytime sleepiness).

The small study sample did not allow for adequate power for the 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 the 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,). While most of these telephone calls were brief (less than 5 minutes), several participants’ telephone calls lasted more than 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 a snack or to engage in conversation beyond the purpose of the 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 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 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, Swedberg, Ekman, Granger, Olofsoon, et al., 2005). This

explanation is plausible, as participants in this study reported 95% adherence rate to daily use of the CES device..

Conclusions

This study was a randomized, double-blind clinical trial exploring whether or not short-term use of CES improved sleep disturbances, depressive symptoms, and caregiving appraisal in elderly caregivers to spouses with Alzheimer's disease. A trend toward statistically significant differences in reports of daily disturbances of sleep was found, with participants in the active CES group demonstrating an improvement in this area. Depressive symptoms decreased in both intervention groups to levels that indicated the absence of depressive symptoms. However, these changes were not statistically significant. 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 from 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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Table 1
Demographic Characteristics of Study Sample

	Active CES (SD) (n =19)	Sham CES (SD) (n =19)	Statistic	p-value
Caregivers				
Age (years)	71.94 (7.78)	76.52 (5.60)	-2.081 [‡]	.045
Gender			1.052 [‡]	.305
Female	14 (73.7%)	11 (57.9%)		
Male	5 (26.3%)	8 (42.1%)		
Education (years)	15.26 (2.92)	14.47 (3.38)	.667 [‡]	.509
Length of time in caregiving role (months)	58.63 (50.75)	57.31 (42.12)	.087 [‡]	.931
Average hours of care provided by caregiver (weekly)	126.21 (60.50)	147.28 (43.01)	-1.238 [‡]	.224
Perception of financial burden				
Yes	5 (26.3%)	6 (31.6%)	.128 [‡]	.721
No	14 (73.7%)	13 (68.4%)		
Care Recipients				
Age	73.89 (8.24)	78.26 (6.13)	-1.853 [‡]	.072
Length of time of memory changes (months)	66.00 (53.17)	62.89 (40.16)	.203 [‡]	.840
Diagnosis			3.310 [‡]	.191
Alzheimer's disease	16	13		
Multi-infarct dementia	1	5		
Unknown	2	1		
Global Deterioration Scale Score (cognitive decline)			6.218 [‡]	.183
3 (mild)	0	1		
4 (moderate)	7	4		
5 (moderately severe)	6	6		
6 (severe)	6	4		
7 (very severe)	0	4		

[‡] = Chi-square

[‡] = t-test

Table 2

Mean Scores on Study Outcomes between Intervention Groups at End of Study (week 4) using One-Way Analysis of Covariance^a and Repeated Measures Analysis of Covariance^b

	Active CES	Sham CES	<i>p</i> -value
^a Sleep Quality (PSQI)	7.80	8.24	.68
^a Sleep Efficiency (PSQI)	2.39	2.6	.74
^a Daily Disturbances (PSQI)	2.34	2.65	.09*
^b Sleep Disturbances (GSDS)	2.12	2.20	.37
^b Sleep Onset Latency (minutes; Sleep Diary)	27.42	33.42	.27
^b Depressive Symptoms (GDS)	9.06	9.45	.24
^b Caregiving Burden(PGCCAS)	36.77	38.75	.66
^b Caregiving Impact (PGCCAS)	22.26	23.10	.59
^b Caregiving Satisfaction(PGCCAS)	11.39	13.36	.11
^b Caregiving Mastery (PGCCAS)	20.39	21.54	.79

* Trend toward statistical significance