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A Novel Medical Device that Relieves Anxiety, Depression and Pain While Improving Sleep in a Population of Teachers

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Abstract

Objectives: This study was conducted to confirm the benefits of Alpha-Stim® cranial electrotherapy stimulation (CES) technology as an effective non-drug treatment for anxiety, mood, sleep, and pain in teachers following a successful pilot study at the Leigh Academy, Dartford, United Kingdom. The second objective was to determine whether the new smartphone app was a reliable method of evaluating the effectiveness, based on the pilot study in the UK, other prior surveys, and more than 100 prospective research studies conducted on Alpha-Stim technology conducted from 1981 through 2019.

Methods: Thirty-five teachers (29 females and 6 males) in the Mineral Wells, Texas Independent School District, volunteered to participate in a study to reduce anxiety, depression, insomnia, and pain by passing a mild electric current with specific waveform characteristics through their brains via electrodes that clip on their ears. It was a six-week open-label design where participants tracked their progress using a new smartphone app to record their symptoms at least five days per week. The subjects were encouraged to use the device for 20-60 minutes any time of day and for any indication.

Results: The statistical analyses revealed highly significant (p values <0.001) for anxiety, depression, insomnia, and pain. The effect size Cohen's d values from a total of 237 treatments were greater than two standard deviations for all outcome measures indicating a high level of practical change from baseline to posttest supporting the capability of Alpha-Stim CES technology in reducing self-perceived symptoms and the ability to monitor progress on the Alpha-Stim app.

Conclusion: This treatment effect with Alpha-Stim cranial electrotherapy stimulation on anxiety, insomnia, depression, and pain was consistent with prior surveys and confirmed the precision of the new app in determining progress from a single treatment and a series of treatments.

Keywords: Cranial electrotherapy stimulation; Alpha-Stim®; Anxiety; Depression; Insomnia; Pain; Teachers; Stress

Background

The purpose of this study was to determine the effectiveness of Alpha-Stim cranial electrotherapy stimulation (CES) for reducing anxiety, depression, insomnia, and pain in a group of teachers over a six-week treatment period by monitoring with a smartphone app. This was the first study using the new Alpha-Stim app to track progress [1-4]. CES is an electrical therapy that involves the use of low-level electrical stimulation of the head through electrodes attached to both earlobes with conducting solution. CES purports to be an effective drug-free treatment of anxiety, depression, insomnia, and pain [5,6].

Ancient Greeks and Romans were the first to use electric eels to produce mild electrical shocks to relieve pain [7]. Alpha-Stim is a medical device in the generic category of cranial electrotherapy stimulation (CES), about the size of a smartphone that is powered by two double A batteries. Alpha-Stim delivers a mild electrical current (100-600 μA) to the brain in a specific patented waveform via ear clip electrodes. The US Food and Drug Administration has approved CES for the treatment of anxiety, depression, and insomnia [6]. During the last 105 years since Robinovitch published the first clinical study on electrical treatment for insomnia, hundreds of studies have been published describing the benefits, effectiveness, and safety of CES for the management of anxiety, depression, insomnia, and pain [8-13].

Until the recent development of a smartphone app that can be retrieved from online app sites, the method of evaluating the effectiveness of CES using Alpha-Stim involved traditional practitioner-patient based research and surveys. For example, under the direction of a practitioner/researcher, a patient was assessed at baseline (pre-treatment), then they used the Alpha-Stim after being given a specified treatment protocol to be used over a prescribed time period by a medical professional. At the end of a specified period, patients were again assessed by clinicians using traditional instruments to assess improvement in the indication targeted for treatment (e.g., anxiety, depression, insomnia or pain). In many of the studies, a sham treatment was given to half the participants, and the active treatment

devices used a very low level of current, so that the treatment was below perception. In such cases, neither the participant nor researcher knew which devices were active or sham, so the studies were classified in the "gold standard" of randomized, double-blind placebo-controlled trials. Consistently, in most such studies, the results were robust [14,15], although the outcomes were not as good as seen in normal use, due to the rigid protocols within a controlled study and desire to mask perceptibility of the active treatment.

Now, Alpha-Stim users can track their symptom level daily or weekly through using the smartphone app to see their progress and compare it to the group means of users in their diagnostic category. While not as reliable as a prospective controlled study, the smartphone app can easily monitor and report daily levels of up to six categories; the four FDA cleared indications and two write-in ones approved for the pilot study. User information captured by the app is stored in a database, and summary information (e.g., percent improvement of the user and user compared to the database) is delivered to participants any time a request is made. In this way, feedback is immediate. When under the supervision of a clinician or with patients and their clinician, they may both access the information and graphics provided by the app.

Introduction

Teaching is a very demanding and stressful profession. A 2018 research study now shows that 93% of teachers are feeling some degree of burnout [16]. When burnout becomes severe, teachers may become ineffective, emotionally exhausted, dissatisfied, negative, and pessimistic [17,18]. At some point when the discontent becomes too burdensome, many will leave the profession. According to Ingersol, Merrill, and Stuckey, more than 41 percent of new teachers leave teaching within five years of entry [19]. With the recognition that burnout is a problem most teachers face, CES treatments offer a possible solution to improve their quality of life by normalizing anxiety, and mood, increasing sleep quality, and managing pain.

CES treatments have been shown to have multiple effects on the brain and body. They produce changes in the electroencephalogram (EEG) where the relative power of alpha (8-12Hz) frequencies increase while reducing the relative power of both delta (0-3.5 Hz) and beta (12.5-30 Hz) frequencies [20]. According to Kirsch & Nichols, increasing alpha waves results in increased relaxation and mental alertness whereas decreasing delta wave activity reduces fatigue and reducing beta waves correlates with reduced anxiety and obsessive/compulsive-like behavior [6].

Through the application of CES in primates with implanted sensors, it was discovered that the electrical current penetrated to every part of the brain [21]. Research studies performed with low-resolution electromagnetic tomography (LORETA) and functional magnetic resonance imaging (fMRI) have shown that Alpha-Stim CES extended to all cortical and subcortical areas of the brain, which reduces excess cortical activation [22]. Excessive cortical activation has been detected in many conditions including anxiety, depression, insomnia, pain, and attention deficit disorder [23-26]. Reducing excess cortical activation with CES is important because it produces changes similar to anxiety medications and antidepressants without all the side effects, addiction, and tolerance seen in drug therapies [6,27]. A reduction of cortical activation can occur even after a single 20-minute CES treatment [6,28]. A single 20-minute session with a CES device can also increase beta-endorphins reducing pain, increasing serotonin, improving mood and sleep, increasing melatonin for sleep, and reducing cortisol levels [6,29]. CES treatments have been shown to produce beneficial effects in normalizing the electrical activity of the brain and in increasing the release of neurotransmitters and hormones safely, effectively and even faster than pharmaceuticals. CES is proving to be one of the most important therapeutic medical options in helping people regulate their emotions, improve anxiety, depression, sleep, and manage pain [6,11,23].

Methodology

In 2017, a pilot study of Alpha-Stim CES with 23 teachers was conducted by John P. Davis' group at the University of Greenwich in London using traditional validated psychometric pre-post testing [1]. The authors concluded that the outcomes were "highly successful." Their results were as follows:

The Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form [30], 21 participants. Higher scores on this scale indicate greater satisfaction, and mean scores on this scale improved from 3.30 (SD= 0.59) to 3.68 (SD= 0.60), and using a paired t-test, this difference was statistically significant in the positive direction, t (20)= -4.15, p= 0.001.

The Pittsburgh Sleep Quality Index [31], 22 participants. Higher scores on this scale indicate worse sleep quality - after the treatment mean scores had decreased from 1.28 (SD= 0.52) to 0.76 (SD= 0.46). A paired t-test also found that this difference was statistically significant in the positive direction, t (20)= 4.48, p< 0.001 which means that participants had better post-treatment sleep quality.

Beck's Depression Inventory [32], 20 participants. Although the researchers did not provide statistical analysis for this test, they stated that scores on the BDI tended to also display a better quality of life in terms of improved sleeping patterns and improved appetite.

Beck's Anxiety Inventory [33,34], 22 participants. There are four sub-scales on this scale. Four paired samples t-test found no significant differences between pre- (M= 0.43, SD= 0.52) and post-treatment (M= 0.34, SD= 0.51) scores in terms of neurophysiological symptoms, t (21)= 1.15, p > .2. However, subjective feelings of anxiety significantly changed between pre- (M= 1.05, SD= 0.85) and post-treatment (M= 0.55, SD= 0.63), t (21) = 4.45, p < 0.001. In addition, panic feelings significantly reduced from pre- (M= 0.46, SD= 1.00) to post-treatment (M= 0.25, SD= 0.32), t (21)= 2.80, p= 0.011. Also, autonomic symptoms significantly reduced from pre- (M= 0.94, SD= 0.76) to post-treatment (M= 0.52, SD= 0.55), t (21)= 3.75, p= 0.001.

Accordingly, volunteer teachers seemed like a good and deserving convenience sample to evaluate the new Alpha-Stim progress tracking app, while simultaneously confirming the British study.

Purpose

The purpose of this study was to examine the effectiveness of monitoring the progress of Alpha-Stim CES treatments using a smartphone application ("app"). Pre and post-treatment measures were recorded on a 0-10 scale for any or all subjective changes in anxiety, depression, insomnia, and pain in a sample of 35 teachers.

Recruitment of Participants

Teachers responded to recruitment efforts sent throughout the Mineral Wells ISD, by flyers and newsletter announcements so the study design was neither randomized nor controlled. The independent

variable in this study was treatment with CES therapy. The Brazos Foundation, an independent charity in Mineral Wells, Texas, paid for participants to be seen by two local nurse practitioners for a health screening and to write orders for Alpha-Stims. Exclusion criteria were pregnancy or having an implanted medical device (e.g., a pacemaker, defibrillator, cochlear implant, spinal cord stimulator or deep brain stimulator). Teachers in good general health were selected for the study. The manufacturer, Electromedical Products International, Inc., donated the devices and the teachers were able to keep the $795 devices for participating in the study. As an incentive for completion subjects were included in a drawing for a $300 gift card. Before participation, all volunteers were briefed regarding specific risks and benefits of CES treatment and completed a statement of informed consent. All personal data was de-identified to ensure patient confidentiality.

Participants were instructed to use the Alpha-Stim in the usual manner, at a comfortable current level for 20-60 minutes daily. The frequency of the waveform was constant at 0.5 Hz, and the intensity was adjustable from 100 – 600 microamps. At pretest (baseline) and posttest, data on outcome measures were recorded as perceived levels of discomfort specific to the teachers' anxiety, depression, insomnia, and pain. The study was conducted for six weeks with a mobile smartphone app, during which time they monitored themselves at least five days per week. Participants were permitted to use the device any time of day and for any indication. At the end of six weeks, they were asked to complete a survey of perceived effectiveness.

The smartphone application used by subjects for reporting their perceived level of insomnia, pain, anxiety, depression, and stress includes an 11-point scale representing a continuous level of measurement expressed as values of 0 – 10. A value of zero (0) signified the absence of any symptoms and a value of ten (10) signified a very high level of discomfort as perceived by the participants.

Results

Many of the teachers only recorded their results a few times while others were more adherent for weeks.

	Baseline		Posttest			
Measure	**M**	**SD**	**M**	**SD**	**t (df)**	**d**
Anxiety (N=100)	6.13	2.4	1.26	0.89	21.26 (100)***	2.95
Depression (N=12)	6.5	1.38	1.58	0.79	9. 56 (11)***	4.5
Insomnia (N=44)	6.03	1.55	1.18	0.45	18.76 (43)***	4.9
Pain (N=66)	6.27	1.72	1.32	0.84	21.74 (65)***	3.9
Stress (N=4)	5.5	0.58	1.75	0.96	5.00 (3)*	2.3

Note. *p < .05. **p < .01. *** p < .001. d = Cohen's d effect size [34] based on the standardized difference between pretest and posttest means. Values are in standard deviations and are interpreted as 0.01 - 0.20= small; 0.30 - 0.59= medium; 0.60 - 1.49= large; > 1.50= very large. For stress, sample size was too small to provide reliable results

Table 1: Differences for measures between pre-test and post-test teachers.

Sample sizes reported in Table 1 reflect the number of pretest and posttest measurement responses by indication. Table 1 provides the results of dependent t-tests for the five outcome measures for teachers. Statistical analyses revealed statistically highly significant (p values <0.001) for anxiety, depression, insomnia, and pain. The effect size (Cohen's d) values from a total of 237 treatments were greater than two standard deviations for all outcome measures, thus indicating a high level of practical change from baseline to posttest supporting the capability of Alpha-Stim CES technology in reducing self-perceived symptoms and the ability to monitor progress on the Alpha-Stim app. No side effects were reported in this study.

Discussion

This study was conducted to confirm the benefits of Alpha-Stim® cranial electrotherapy stimulation (CES) technology as an effective non-drug treatment for anxiety, mood, sleep, and pain in teachers following a successful pilot study at the Leigh Academy, Dartford, United Kingdom [1]. The second purpose of this study was to examine the effectiveness of monitoring Alpha-Stim CES treatment using a smartphone application. Outcome measures were anxiety, depression, insomnia, pain and stress in a sample of teachers. The study design included a single subject convenience sample design using one pretest-posttest trial with teachers choosing to participate or not (i.e., self-selecting into participation). Although anxiety was the most selected condition treated and insomnia showed the greatest improvement in this study that was followed closely by depression, all the results were highly significant supporting the capability of Alpha-Stim CES technology in reducing self-perceived symptoms and the ability to monitor progress on the Alpha-Stim app.

Limitations

A limitation of this study is self-selection by teachers into the study. Self-selection into a study (i.e., no randomized sample selection process) is widely known to contribute to bias in parameter estimation. In other words, reported outcomes might not be reliable and valid because subject participation affects how they report their outcomes. A second limitation is the lack of a control or comparison group against, which results could be statistically and practically compared. However, these variables were controlled in many other, prospective randomized studies using Alpha-Stim CES for the same indications in various civilian and military populations.

Taken together with Davis' study of teachers in the UK [1], this study provides confirming evidence that a safe and effective medical technology exists to improve the quality of lives for teachers, improving their anxiety, mood, sleep, and pain. This may decrease teacher burnout along with the associated absences and improve job satisfaction increasing retention while making teachers less pessimistic; thereby enabling them to be more effective in their profession.

Conclusion

This study and the UK teacher's study have established that Alpha-Stim cranial electrotherapy stimulation (CES) technology is a successful non-drug treatment of anxiety, depression, and insomnia. For individuals concerned about the side effects of drugs, Alpha-Stim is a good option. The Brazos Foundation, an independent charity in Mineral Wells, Texas, paid for the health screenings and Electromedical Products International, Inc. provided the devices used in the study free of charge.

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