CLEARINGHOUSE
FOR MILITARY FAMILY READINESS

Cranial Electrical Stimulation (CES) and the Alpha-Stim Cranial Electrotherapy Stimulation Device:

Rapid Literature Review

Clearinghouse Technical Assistance Team

As of October 30, 2020

This material is the result of partnership funded by the Department of Defense between the Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy and the USDA's National Institute of Food and Agriculture through a grant/cooperative agreement with Penn State University

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Executive Summary

This rapid literature review was conducted in response to a request for information regarding use of Alpha-Stim machines, a cranial electrotherapy device, for the treatment of mental health conditions. This review provides a brief overview of cranial electrotherapy stimulation (CES) treatment and specific information on two of the most common CES devices: the Alpha-Stim cranial electrotherapy device and the Fisher Wallace Stimulator.

This report includes the following elements:

- Background information on CES treatments,
- Examples of CES devices: the Alpha-Stim cranial electrotherapy device and the Fisher Wallace Stimulator,
- Evidence of effectiveness for CES treatments,
- Studies that examine CES in Service members and veterans, and
- Additional online resources.

Please note that this rapid literature review provides a preliminary examination of the research. Thus, given the brief timeline, this report is not intended to serve as a comprehensive review of the literature, and the resources provided are not endorsed by the Clearinghouse for Military Family Readiness at Penn State. Rather, the information about the resources are provided for you to help you make a data-driven decision.

Introduction

The Technical Assistance (TA) team at the Clearinghouse for Military Family Readiness at Penn State (Clearinghouse) conducted a brief, rapid literature review on the topic of cranial electrical stimulation (CES) and specifically two CES devices: the Alpha-Stim cranial electrotherapy device and the Fisher Wallace Stimulator. Research that examines these types of treatments were identified by searching peer-reviewed journal articles and grey literature. Search queries included various combinations of the following terms: Alpha-Stim, Fisher Wallace Stimulator, Cranial Electrical Stimulation, and Cranial Electrotherapy.

Background

Cranial Electrical Stimulation (CES) is defined as the use of small electrical current pulses to stimulate brain activity for the treatment of insomnia, anxiety, depression, and pain (Jonas, 2018). CES works by stimulating alpha brain waves - the brain activity that provides a sense of calmness, alertness, mind/body integration, and mental coordination for the body (Cosio & Castellow, 2020). The presence of alpha brain waves overrides other brain activity or beta waves, which are associated with feelings of stress. In other words, the electrical current pulses generated by CES are intended to increase alpha brain activity and decrease beta activity. The result is a shift in one's brain from a stressed state to a resting or meditative state.

Treatments of CES were derived from Transcranial Electrical Stimulation (tES) and Electrosleep (ES). These treatments applied currents to the brain and were used in research and clinical practice in the early 1900s (Guleyupoglu et al., 2013). In 1977, the U.S. Food and Drug Administration (FDA) reviewed ES and formally identified it as a form of treatment in 1978.

Because CES was grandfathered in from other forms of tES, some debate still exists over its status with the FDA (Guleyupoglu et al., 2013). In 1976, the FDA added the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, which was created to ensure the safety of medical devices. Because CES devices were in distribution before 1976, they were considered "pre-amendment devices," and, therefore, they were exempt from the FDA's Premarket Approval (PMA) Process. Their exemption from the PMA Process meant that the CES devices did not have to prove their effectiveness in randomized controlled studies before the device was marketed to the public (U.S. Food & Drug Administration, 2018).

The FDA website (2018) includes a clause in section 501(k) that states these devices can be "cleared," which involves a less extensive process than being "approved." However, as an approved device, these CES devices are still determined by the FDA to be a safe treatment for insomnia, anxiety, depression, and pain. Note, the devices have not completed the formal PMA and, therefore, have not obtained the highest classification of the FDA (Knotkova & Rasche, 2015).

Of the CES treatments available and reviewed in the research literature, the Alpha-Stim cranial electrotherapy device and the Fisher Wallace Stimulator were the most commonly cited CES devices. Both devices are described in more detail below.

The Alpha-Stim Cranial Electrotherapy Device

According to the Electromedical Products International webpage (n.d.), the Alpha-Stim CES device is a handheld medical apparatus that is FDA cleared to treat anxiety, depression, insomnia, and pain. It uses small clip electrodes that are attached to a person's earlobes to administer a natural level of microcurrent. This current impacts groups of nerve cells in the user's brain in order to reduce pain, encourage better sleep, and relieve anxiety and depression.

The ear clip electrodes use felt pads, which are moistened with a mineral solution and are, then, attached to the patient's earlobes. After turning on the machine, a current between 100-500 microamperes is transmitted to the brain. Although one might feel a mild tingling sensation or a slight dizzy feeling, the current should never be raised to a level that is uncomfortable for the patient. This treatment can be done daily or every other day for 20-60 minutes. It is portable and non-invasive, and it can be used in addition to psychotherapy (Scurfield & Platoni, 2013).

There are two versions of the Alpha-Stim device: Alpha-Stim AID and Alpha-Stim M. The Alpha-Stim AID device focuses on remediating anxiety, insomnia, and depression, while the Alpha-Stim M device treats the same conditions as the AID device, and treats acute, chronic, and post-traumatic pain. Currently, in the United States, users of the Alpha-Stim device need a prescription from a licensed healthcare professional to purchase either of these machines. The Alpha-Stim AID retails for $795, while the Alpha-Stim M is listed at $1,195. After obtaining a prescription, there are multiple ways to purchase these devices: visit https://www.alpha-stim.com/shop/ and complete an online order, call in an order to the company at 1-800-367-7246, or fax an order form found on the website (the fax number can be obtained by calling the phone number listed below). In addition, finance options are available. Alpha-Stim is available in over half of the Department of Veterans Affairs (VA) and Department of Defense (DoD) centers in the United States, and more information is available for Service members by calling 1-800-FOR-PAIN and selecting option 2.

More information about this device is available on the company's website found here: https://www.alpha-stim.com/.

The Fisher Wallace Stimulator

According to the Fisher Wallace Laboratories website (2020), the Fisher Wallace Stimulator, similar to the Alpha-Stim machine, delivers a gentle electrical pulse, which produces serotonin and alpha waves that are used to treat insomnia, anxiety, and depression. This small machine is FDA cleared and can be used in conjunction with other forms of medication. Where the Alpha-Stim machine uses clips attached to a patient's earlobes, the Fisher Wallace Stimulator uses a headband to hold the two moistened sponge applicators in place on either side of the head. Note, the Fisher Wallace Stimulator does not include a pain management option; the Stimulator only focuses on insomnia, anxiety, and depression.

This device indicates use once or twice a day for 20 minutes at a time until symptoms are completely resolved, which means the patient is in full remission. In addition, the patient may continue use of the device a few times a week to continue accessing the benefits that the machine offers. During treatment, patients can simply rest or engage in minimal activities such as watching TV or reading.

Just like the Alpha-Stim device, the Fisher Wallace Stimulator requires a licensed provider to authorize its purchase. After obtaining authorization from a physician, users can purchase the stimulator for $799 on the company's website at https://www.fisherwallace.com/collections/all. Financing is available through the Klarna "Slice It" option, which allows the patient to pay for the device over a period of time. The company also offers a 30-day money back guarantee statement if the consumer is not satisfied with the results. Since 2009, over 10,000 healthcare providers have prescribed the Fisher Wallace Stimulator.

More information about this device is available on the company's website found here: https://www.fisherwallace.com/.

Evidence

A systematic review (Shekelle et al., 2018a) of 26 randomized control trials found insufficient evidence to support the view that CES treatments improve the following conditions: fibromyalgia, headache, neuromusculoskeletal pain, degenerative joint pain, depression, and insomnia. However, the review also consistently noted a lack of adverse effects from CES treatment. Studies were limited by a lack of information on patients'

existing treatments and by the study design (e.g., small sample sizes, insufficient study duration), so the results of these studies should be interpreted with caution.

Since Shekelle's 2018 review, additional research has emerged around CES effectiveness. In a study of patients who were diagnosed with moderate to severe generalized anxiety disorder, patients using Alpha-Stim CES treatment showed improvement in anxiety, quality of life, and depression. Nearly 45% of these patients achieved remission of symptoms, and 63% of the patients experienced some improvements in their perceived anxiety symptoms with Alpha-Stim CES treatment (Morriss et al., 2019). In the same study, improvements in quality of life and drops in insomnia and depression were observed (Morriss et al., 2019).

However, throughout the research, noticeable limitations were observed that compromise the ability to fully recommend CES as an effective form of treatment for insomnia, anxiety, depression, and pain. To date, much of the research has consisted of clinical studies that lack a rigorous study design (Knotkova & Rasche, 2015; Shekelle et al., 2018a). Of the research studies identified, many lacked a control group. In 21 of the randomized control trials that were conducted, Shekelle et al. (2018a) addressed concerns with the small number of subjects (i.e., less than 30 participants for each study). The lack of ethnic, age, and gender diversity within the studies also limits the ability to generalize results to diverse populations (Morriss & Price, 2020).

CES Treatment and Military Service Members

Since the early 2000s, the DoD and the VA have offered CES treatment for Service members who experience insomnia, anxiety, depression, post-traumatic stress disorder (PTSD), and pain. The VA Evidence-based Synthesis Program (ESP) also published a systematic review on the effectiveness and risks of CES for the treatment of pain, depression, anxiety, PTSD, and insomnia for the VA (Shekelle et al., 2018b). To access a copy of the report please visit: https://www.hsrd.research.va.gov/publications/esp/CES-REPORT.pdf

In addition to the ESP research above, the following three studies focus on military Service members and veterans and their experiences with CES treatment. Each study is listed below with a brief summary. The Clearinghouse can send you the published studies, if you would like a copy of any of the research articles.

Research on CES Treatment with Service members and Veterans

Hare, J. P., Misialek, L. H., Palis, K., & Wong, C. (2016). Using cranial electrotherapy stimulation therapy to treat behavioral health symptoms in a combat operational setting. *Military Medicine*, *181*(11-12), 1410-1412.

- This article examines CES in terms of its effectiveness in treating combat operational stress reactions (COSR). Due to its low cost and practicality for use in a deployed setting and it creating less stigma than medication or therapy, CES was considered to be a beneficial option for Service members.

Kirsch, D. L., Price, L. R., Nichols, F., Marksberry, J. A., & Platomi, K. T. (2014). Military service member and veteran self reports of efficacy of cranial electrotherapy stimulation for anxiety, posttraumatic stress disorder, insomnia, and depression. *The United States Army Medical Department Journal.* 46-54.

- This study of 152 participants analyzed Service members' and veterans' perceptions of CES in regard to its safety and effectiveness. It concluded that CES was considered to be a safe, noninvasive, nonpharmacologic treatment for insomnia, anxiety, depression, and PTSD for Service members and veterans.

Tan, G., Dao, T. K., Smith, D. L., Robinson, A., & Jensen, M.P. (2010). Incorporating complementary and alternative medicine (CAM) therapies to expand psychological services to veterans suffering from chronic pain. *Psychological Services, 7*(3), 148–161.

- This article looks at CAM therapies for veterans who had chronic pain and were treated using CES to remedy the following conditions fibromyalgia, tension headaches, and other chronic pain. Based on the studies observed, CES was thought of as a form of treatment that should be considered due to the low cost, lack of side effects, portability, and ease of administration.

Conclusion

Based upon the findings of this rapid literature review, additional research needs to be completed to make a determination on the effectiveness of the use of CES devices, such as the Alpha-Stim machine, on treating mental health conditions. While evidence shows some promise for CES in treating conditions such as anxiety with depression, the insufficiently rigorous study designs limit the ability to validate this form of treatment for anxiety with depression and other conditions including insomnia, depression, or pain management. However, current evidence also demonstrates a lack of serious side effects from CES treatment.

Additional Assistance

The TA specialists at the Clearinghouse provide support to professionals as they examine and make informed decisions about which programs fit specific situations and are worth the investment. Whether connecting one with the resources and tools to conduct a needs assessment in a specific community, suggesting the best evidence-based program or practice for a certain situation, or developing an evaluation plan, the TA team of experts is a call or email away.

Please visit the Clearinghouse's website at www.militaryfamilies.psu.edu or call 1-877-382-9185 to speak with a TA specialist.

Suggested Citation

Clearinghouse for Military Family Readiness at Penn State. (2020, October). *Cranial Electronic Stimulation (CES) and the Alpha-Stim cranial electrotherapy stimulation device: Rapid literature review*. [Literature Review]. Clearinghouse for Military Family Readiness at Penn State.

References

Cosio, D. & Castellow, J. (2020). A Mixed Methods Exploration of Electrical Stimulation in Veterans with Fibromyalgia Symptoms & Affective Disorders. Journal of Affective Disorders, 274, 956-963.

Electromedical Products International. (n.d.). *Alpha-Stim*. https://www.alpha-stim.com/

Fisher Wallace Laboratories. (2020). *Rapid depression, anxiety, and insomnia therapy*. https://www.fisherwallace.com/

Guleyupoglu, B., Schestatsky, P., Edwards, D., Fregni, F., & Bikson, M. (2013). Classification of methods in transcranial Electrical Stimulation (tES) and evolving strategy from historical approaches to contemporary innovations. *Journal of Neuroscience Methods*, *219*(2), 297–311. https://doi.org/10.1016/j.jneumeth.2013.07.016

Jonas, W. B. (2018). Cranial electrical stimulation: What is it, and should we use it in practice?. *Annals of Internal Medicine*, *168*(6), 446–447. https://doi.org/10.7326/M17-3420

Knotkova, H., & Rasche, D. (Eds.). (2014). *Textbook of neuromodulation: Principles, methods and clinical applications*. Springer. https://doi.org/10.1007/978-1-4939-1408-1

Morriss, R., & Price, L. (2020). Differential effects of cranial electrotherapy stimulation on changes in anxiety and depression symptoms over time in patients with generalized anxiety disorder. *Journal of Affective Disorders*, *277*, 785–788. https://doi.org/10.1016/j.jad.2020.09.006

Morriss, R., Xydopoulos, G., Craven, M., Price, L., & Fordham, R. (2019). Clinical effectiveness and cost minimisation model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalised anxiety disorder. *Journal of Affective Disorders*, *253*, 426–437. https://doi.org/10.1016/j.jad.2019.04.020

Scurfield, R. M., & Platoni, K. T. (2013). *Healing war trauma: A handbook of creative approaches*. Routledge/Taylor & Francis Group.

Shekelle, P. G., Cook, I. A., Miake-Lye, I. M., Booth, M. S., Beroes, J. M., & Mak, S. (2018a). Benefits and harms of cranial electrical stimulation for chronic painful conditions, depression, anxiety, and insomnia a systematic review. *Annals of Internal Medicine*, *168*(6), 414–421. https://doi.org/10.7326/M17-1970

Shekelle, P. G., Cook, I., Miake-Lye, I. M., Mak, S., Booth, M. S., Shanman, R., & Beroes, J. M. (2018b). The effectiveness and risks of cranial electrical stimulation for the treatment of pain, pepression, anxiety, PTSD, and insomnia: A systematic review. *VA Evidence-Based Synthesis Program Reports*, 05–226.

U.S. Food & Drug Administration. (2018, August 23). *PMA approvals*. https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals