

## **Transdermal electrical neurostimulation therapies in psychiatry: A review of the evidence**

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This is a head to head product review, published as a CME article in the psychiatric literature, of Alpha-Stim CES technology, the Fisher Wallace CES device, and Thync.

The authors coin the term “transcranial electrical neurostimulation (TEN)” and state that this is the first review of the claims being made for these devices defined as those “that claim to directly address discrete mental health conditions and can be used without the guidance of a trained professional.” It reviewed three domains: “efficacy/effectiveness, usability/safety, and mechanics.”

This annotated abstract of the review is limited to the Alpha-Stim and Fisher Wallace devices because Thync is not cleared by FDA for marketing. The other two devices are FDA cleared for the indications of anxiety, depression and insomnia by prescription and have undergone decades of FDA scrutiny.

After a brief discussion of the Thync, the authors write (references removed in this abstract), “In comparison, the Alpha-Stim device has a larger and more diverse empirical base. A succession of randomized controlled trials has established some degree of efficacy for the device in syndromes as varied as fibromyalgia and insomnia, as well as a number of psychiatric conditions. Several open clinical trials and case studies have also yielded positive results. In terms of the effectiveness of the Alpha-Stim in treating psychiatric disorders, a study found that 5 weeks of treatment with an Alpha-Stim moderately reduced scores on the Hamilton Rating Scale for Anxiety and Hamilton Rating Scale for Depression in people with a primary anxiety disorder. Moderate reductions in depression-related scores on the Beck Depression Inventory (BDI) and the Brief Symptom Inventory were also found in a sample of sheriff's officers. An open study of military service members and veterans found that, for those responding to the survey, the Alpha-Stim was effective in reducing subjective impairment resulting from generalized anxiety, posttraumatic stress disorder, insomnia, and depression. A pilot study of people with primary anxiety disorders also yielded positive results in the moderate range. Additionally, a retrospective study found mixed results in a cohort of patients with chronic bipolar disorder, in that Clinical Global Impression scores improved significantly while having no reliable effect on mood symptoms. Finally, an older open study found positive effects of Alpha-Stim use in people with anxiety disorders.”

“The Fisher Wallace Stimulator has been applied to a wide range of physical illnesses. However, its effectiveness in the treatment of mental illness has been poorly studied. Only one extant publication could be located that specifically tested the Fisher Wallace Stimulator—a pilot study involving people with depressive symptoms in the context of bipolar II disorder found moderate but brief improvement in subjective symptom severity based on scores on the BDI.”

The authors write little about safety but conclude that “...there is a large corpus of safety and usability literature that finds low-amperage tDCS and TEN devices to be well-tolerated by users.”

As to mechanisms it states, “Developers of Alpha-Stim posited that electrical stimulation of different branches of cranial afferent nerves modulates acetylcholinergic and serotonergic systems projecting via the raphe nucleus onto various thalamic nuclei. This pathway is described as having direct effects on mood, anxiety, and cognition. In contrast, investigators using the Fisher Wallace Stimulator have not suggested a specific method of action...”

The authors conclude by stating that “In our view, a convincing case had been made that TEN devices are safe and do not cause significant discomfort, but there is a need for high-quality, rigorous studies involving larger samples, better participant selection, more consistent electrostimulation mechanics, and replication of findings...User-controlled TEN appears to be a promising but emergent intervention for mental health conditions, and producing a more robust empirical basis should be a top priority for developers and interested researchers looking for an innovative option for treatment.”

<http://www.healio.com/psychiatry/journals/psycann/2016-10-46-10/%7B2bd1f5ed-2915-41db-93a1-316ff053f115%7D/transdermal-electrical-neurostimulation-therapies-in-psychiatry-a-review-of-the-evidence>