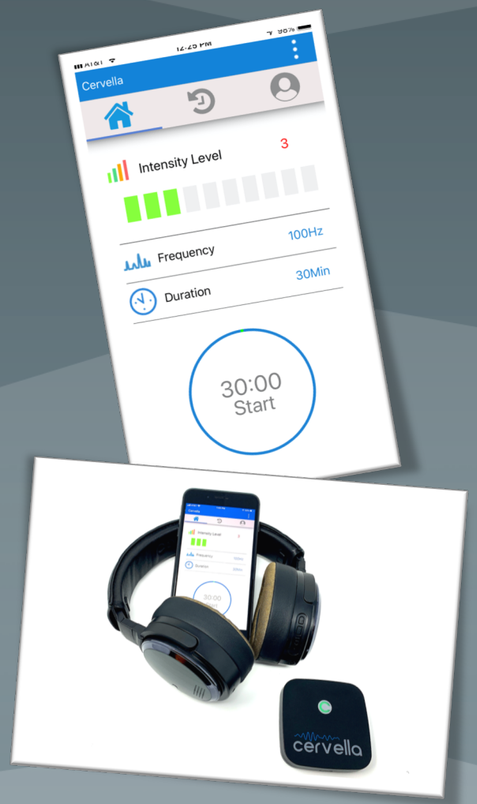
cervella™



Q: Who should not use Cervella?

A: Cervella should not be used by children without adult supervision. Cervella may affect the operation of implanted devices (e.g. cardiac pacemakers or defibrillators). Safety of stimulation has not been established for women who are pregnant. Always consult your healthcare provider before using Cervella.

innovative neurological devices llc

FDA 510(k)

Q: How soon will I start feeling better?

A: Most patients start feeling the positive effects of cranial electrotherapy stimulation within the first week. Note that results vary and are dependent on your condition. Anxiety is often reduced after a single treatment but may reoccur so consistent treatment sessions are recommended. Many patients suffering from anxiety find it useful to use Cervella at the onset of anxiety or before a high stress situation.

Patients with depression will often see improvements in a few weeks, but patients should continue to use Cervella as directed by their healthcare provider. Insomnia is often reduced after few treatments but, like depression, consistent treatment sessions are recommended even when you are feeling better. Always consult your healthcare provider before starting Cervella and follow the treatment plan as directed.

Q: Is Cervella covered by insurance?

A: Insurance coverage varies depending on type of insurance so we suggest that you inquire with your insurance company. Please contact us for assistance with the billing codes and a template for the Letter of Medical Necessity. In addition, you can use your HSA or FSA or take advantage of the six months same as cash offer. Note: We cannot bill your insurance provider directly for Cervella so you would have to purchase the device first and then seek reimbursement.

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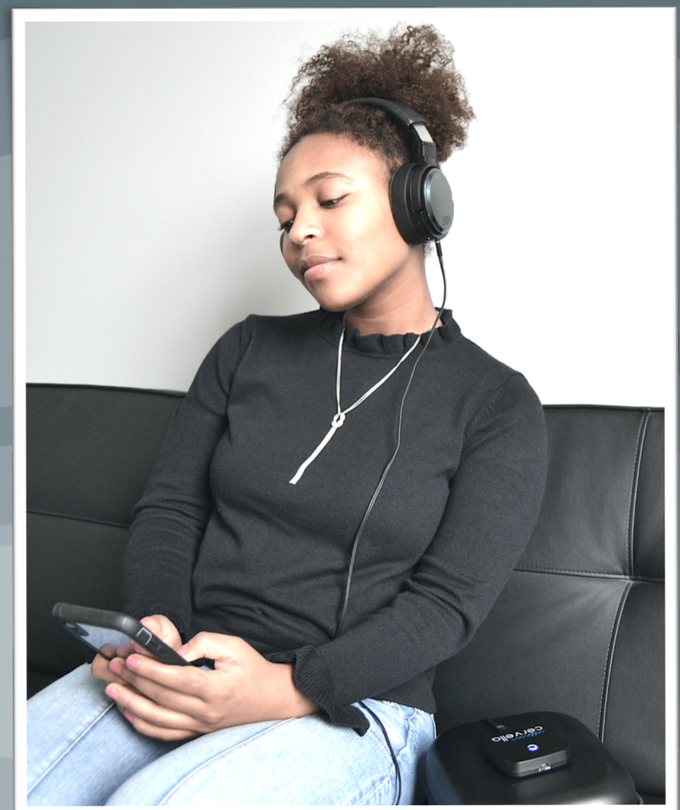
cervella

cranial electrotherapy stimulator



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cervella™

cervella is a medical device for non-drug treatment of anxiety, insomnia, and depression

Q: What is Cervella?

Cervella is an FDA-cleared award-winning medical device for non-drug treatment of anxiety, depression, and insomnia. Cervella works by delivering micro pulses of electric current through patient's brain via conductive electrodes that are integrated into the ear cushions of an audio headset. Cervella is controlled via an app installed on patient's smart device. During treatment, which typically lasts 30 minutes, patient can listen to music via a dedicated Bluetooth connection or use the active noise cancellation feature of the headset. In short, Cervella can be used during school, work, study, or play.

How does Cervella work?

Cervella is a type of Cranial Electrotherapy Stimulator (CES) medical device. Cervella transmits small pulses of electric current across patient's brain via a pair of conductive electrodes placed on patient's head. CES devices are approved by the FDA for treatment of insomnia, depression, and anxiety. They exhibit very good efficacy, do not present significant side effects, and they are not habit-forming.

According to research, the micro current that is delivered by Cervella has several effects on the brain: it affects the Default Mode Network (DMN), alters the endogenous brain oscillations, and causes change in neurotransmitter levels such as serotonin and β-endorphin.

Cervella is a good alternative to drug therapies, especially for patients that respond poorly to anti-depressant drugs or experience significant side-effects with drug-based therapies. Cervella can also be used in conjunction with drug or cognitive therapies.

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Clinical Evidence

Cranial Electrotherapy Stimulation has been present in medical use for several decades. Consequently, there is a large body of clinical evidence documenting the efficacy of CES for treatment of anxiety, depression, and insomnia.

Below, we present a sample of a recent double-blind clinical trial (N=115):

** Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. Journal of Affective Disorders. 2014; 164:171-177.*

"**Results:** Analysis of covariance revealed a significant difference between the active CES group and the sham CES group on anxiety ($p=0.001$, $d=0.94$) and on depression ($p=0.001$, $d=0.78$) from baseline to endpoint of study in favor of the active CES group.

Conclusions: CES significantly decreases anxiety and comorbid depression. Subjects reported no adverse events during the study. The large effect sizes for the effects of CES on anxiety and comorbid depression reveal a favorable risk/reward ratio supporting the use of CES for the treatment of anxiety and comorbid depression in evidence-based practice.*"