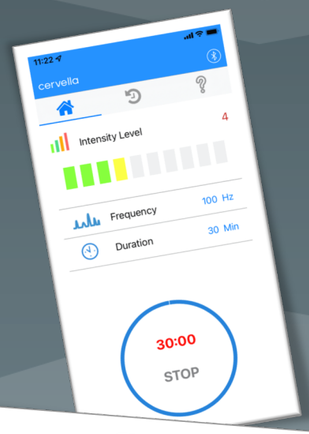
cervella™



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.

Insomnia is often reduced after few treatments but, like anxiety, 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: Who should not use Cervella?

A: Cervella should not be used by children without adult supervision or people with metal implanted in or around the head. 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.

Q: Is Cervella covered by insurance?

A: Insurance reimbursement varies depending on type of insurance so we suggest that you inquire with your insurance provider. 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 funds or take advantage of the six months same as cash offer. Note: We cannot bill your insurance provider directly for Cervella so you will have to purchase the device first and then seek reimbursement.

innovative neurological devices llc

FDA 510(k)

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US PATENT 10,857,360

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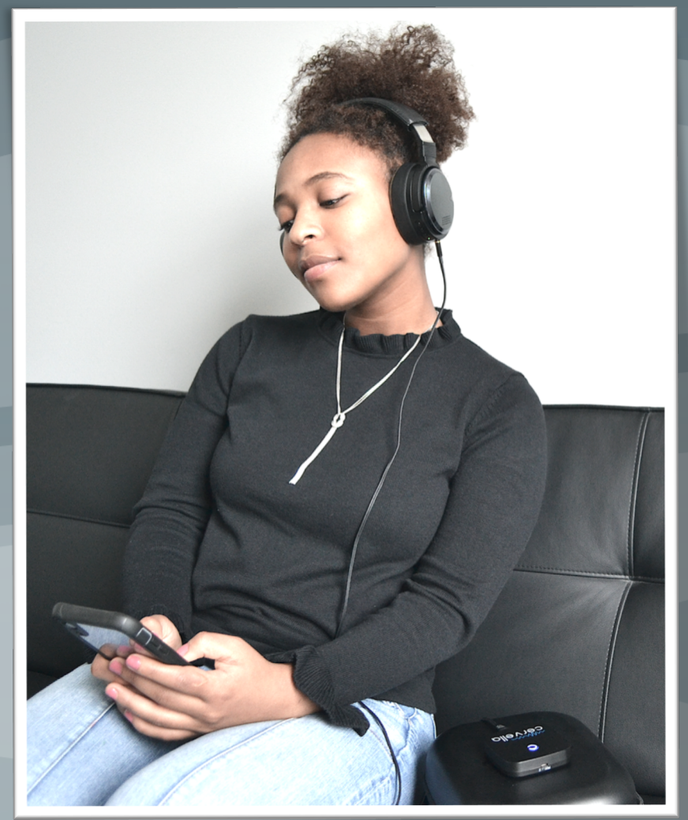
cranial electrotherapy stimulator



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

Q: What is Cervella?

Cervella is an FDA-cleared, patented, award-winning medical device for non-drug treatment of anxiety 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 (cleared) by the FDA for treatment of anxiety, insomnia, and depression (via PMA). 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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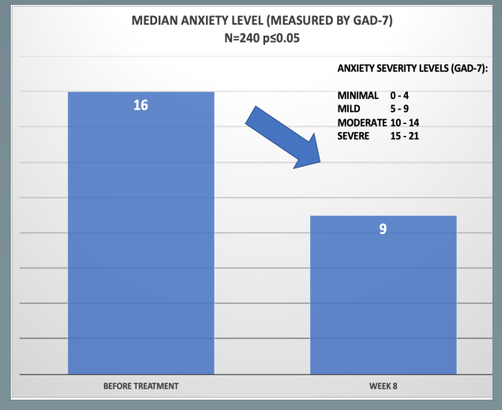
Clinical Evidence

Cranial Electrotherapy Stimulation has been 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 results of observational study of 240 randomly-selected patients who were diagnosed with Anxiety and/or Insomnia disorders and prescribed the Cervella device. Patients were instructed to use Cervella daily for 30 minutes for 8 weeks.



Patients who have been diagnosed with Anxiety, were evaluated using GAD-7 (General Anxiety Disorder-7). Patients who have been diagnosed with Insomnia, were evaluated with SQS (Sleep Quality Scale).

Conclusion: Overall, 92% of patients reported that the Cervella was beneficial with treatment of the underlying conditions. This is evidenced as a statistically-significant reduction of the conditions as measured by GAD-7 and SQS. Furthermore, there were no major adverse events and the minor adverse events were present in fewer than 1% of the patients.