

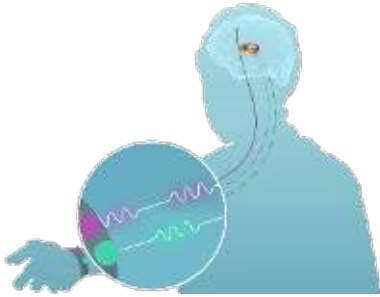
Frequently Asked Questions



Use of Cala Trio™ Therapy

Q. How does Cala Trio therapy work?

The Cala Trio device stimulates the median and radial nerves at the wrist using specialized electrodes. The 40-minute stimulation session excites the A-beta fibers in the median and radial nerves to reach the VIM in the thalamus--a key relay in the brain's central tremor circuit.



Q. How is Cala Trio therapy customized for each patient's tremor?

During set up, Cala Trio therapy is calibrated when the patient performs a prescribed "Tremor Task." This allows the device to characterize the patient's tremor and individualize the stimulation.

The accelerometers in the device measure their motion and determine the best pattern to deliver the stimulation.

Q. Will Cala Trio therapy take the place of the current treatment for ET?

Many patients in Cala Health's clinical studies have continued to take medication for their tremor while using Cala Trio therapy. Other patients used Cala Therapy as a monotherapy. It was difficult to assess the effect of the device compared to medication. Cala Health continues to study Cala Trio therapy to better understand its use and efficacy in these situations.

Q. Do patients wear Cala Trio therapy on only one wrist?

Yes, separate devices are available to either treat the right or left hand. The physicians' indicates this this on the prescription. The nerves in the wrist are not symmetrical, so a device designed for the right side would not work on the left hand.

Furthermore, the clinical trials evaluated Cala Trio therapy in one hand only. It is unknown if use on both hands will provide better, worse, or similar benefits. Cala Health continues to study Cala Trio therapy to better understand its use and efficacy and will share insight as we learn.

Q. How often can a patient use Cala Trio therapy during the day?

Cala Trio therapy is an on-demand therapy, designed to allow the patient to stimulate the nerves throughout the day based on the frequency of their tremors. A stimulation session is 40-minutes, and at least five sessions can be completed when fully charged. The patient should begin therapy approximately 40-minutes before any activity when they desire temporary reduction in their tremor.

Availability of Cala Trio™ Therapy

Q. Where is the Cala Trio therapy available?

Cala Trio therapy is currently available by prescription in the US; the wearable neuromodulation device can be prescribed through an in-person HCP consultation or telemedicine appointment.

Q. How is Cala Trio being distributed?

Cala Health's vertically integrated commercial model is reshaping prescription therapy delivery. Cala Trio therapy can be prescribed through an in-person visit to their healthcare professional or telemedicine appointment; physicians in the US then submit the prescription directly to Cala Health. Therapy is shipped directly to the patient's home, and Cala Health therapy specialists support patients via phone, video, or user portal. Cala Health is a licensed durable medical equipment company.

Q. Does Cala Trio therapy have insurance coverage?

Cala Health can now assist some insured patients with their healthcare benefits ultimately leading to affordable therapy. Cala Health anticipates new coverage policies will be developed by Medicare, Medicaid, and commercial payors such as Aetna, Blue Cross, Blue Shield, and United Healthcare.

Cala Health is committed to helping patients access Cala Trio therapy by working directly with them and their insurance provider. Cala Health also works with patients and their healthcare providers to assemble the required medical necessity documentation and perform benefit verifications to estimate the patient's out-of-pocket costs. With information and support from Cala Health, patients can decide if they want Cala Health to submit a claim directly to their insurance provider on their behalf.

Q. What is the cost of the Cala Trio therapy?

Cala Health offers payment options to qualified patients to accommodate patients' financial situations. Insurance companies have been paying for Cala Trio devices for individual patients. The out-of-pocket cost depends on the individual plan the patient is enrolled in.

The PROSPECT Study

Q. What is PROSPECT?

PROSPECT (**PRO**spective study for **SymPT**omatic relief of **Essential** tremor with **Cala** Therapy) is the largest therapeutic study ever conducted in ET. Cala Therapy, now marketed as Cala Trio, was used in the study

Q. What is the PROSPECT study design?

PROSPECT was a prospective, 26-center, single-arm study designed to evaluate the symptomatic relief from hand tremor in ET with repeated use of Cala Therapy. Patients were instructed to use the device for 40-minute sessions twice daily for three months. The device was calibrated to each patient's tremor frequency and delivered patterned electrical stimulation to nerves through the skin. The study enrolled 263 patients with an average duration of ET symptoms lasting over 25 years.

Q. What are the topline findings of the PROSPECT study?

PROSPECT met its co-primary and secondary endpoints, achieving statistically significant improvements in symptomatic relief of ET in the treated hand at three months compared to baseline. Physician-rated (TETRAS) and patient-rated (ADL) endpoints were achieved.

Data shows,

- 62% of patients improved from 'Severe' or 'Moderate' tremor at the beginning of the study to 'Mild' or 'Slight' tremor
- 68% of patients who self-rated as having "Severe or Moderate" difficulty in their activities of daily living self-rated as "Mild" or better at the end of the study.
- 64% of patients reported having persistent relief for an average of 94 minutes (standard deviation = 138; median = 60)

Secondary endpoint analysis of motion sensor data obtained by Cala Therapy showed that 54% of patients experienced greater than 50% improvement in tremor power for the three-month study. Over 21,000 stimulation sessions were collected and analyzed. Clinical and patient global impression of improvement showed that 68% of clinicians and 60% of patients rated improvement at three months. Significant improvement was reported in the Quality of Life in Essential Tremor Questionnaire (QUEST) scores. Transient device-related adverse events such as wrist discomfort, skin irritation, or pain occurred in 18% of patients. None required medical intervention.

Isaacson SH, et al. Tremor and Other Hyperkinetic Movements. 2020;10:29. doi:10.5334/tohm.59. As measured by Cala device following three months of repeated home use in 205 patients with essential tremor who completed the study. Many participants were also taking medication for their tremor and it was difficult to assess the effect of the device compared to medication.

Food and Drug Administration (FDA) has cleared the Cala Trio K203288.

Indications for Use Cala Trio therapy is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

Contraindications

Cala Trio therapy should NOT be used by patients with an implanted electrical medical device, those with suspected or diagnosed epilepsy or other seizure disorders, or used on the treated wrist with diseased skin (e.g., swollen, infected, inflamed areas, or open wounds), or by patients who are or may be pregnant.

Warnings

To avoid the risk of electric shock, burns, electrical interference, or death, do not use Cala Trio if you have an implanted electrical medical device or implanted metal in the wrist. Do not use Cala Trio: while sleeping, driving, bathing, or operating machinery; on or near the neck, chest, or head; over open wounds, rashes, or inflamed skin.

Adverse Reactions

Patient-reported side effects include: mild to moderate skin irritation including electrical stimulation burns, redness, and/or itching where the device touched the skin.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Please refer to the safety information at CalaTrio.com/Safety for a complete listing of warnings and cautions.

