

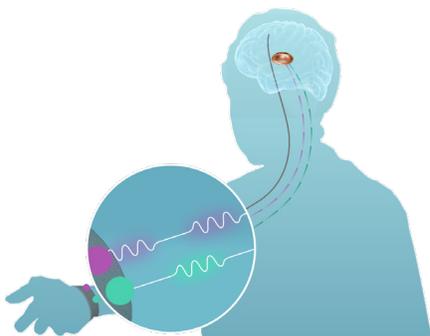
# Frequently Asked Questions



## Use of Cala Trio™

### Q. How does Cala Trio work?

Cala Trio therapy delivers electrical stimulation to nerves in the wrist. These nerves project from the wrist to central brain networks that are responsible for generating hand tremor in ET. Stimulation of the nerves in the wrist is thought to disrupt the central neural network causing hand tremors and provide temporary and meaningful tremor reduction in the treated hand.



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

During set up, Cala Trio 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 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. 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 on only one wrist?

Yes, separate devices are available to either treat the right or left hand. The physicians' indicates this on the prescription. The nerves in the wrist are 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 during the day?

Cala Trio 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™

### Q. Where is the Cala Trio available?

Cala Trio 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 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 have insurance coverage?

Cala Trio is a novel technology, first-in-class therapy. Insurance coverage will take at least one year. During this time, it is important to Cala Health's mission to make ET therapy accessible to consumers. There are payment options to meet the needs of as many consumers as possible. All payment plans include a 60-day evaluation program. Cala Trio is eligible as a qualified medical expense for health savings and flexible spending accounts.



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

The 2020 MSRP is \$3,200 for the Cala Trio neuromodulation device plus a \$157 monthly band subscription. Cala Health offers payment options to qualified patients to accommodate patients' financial situations.

### The PROSPECT Study

*NOTE: Cala Therapy, now marketed as Cala Trio, was used in the study*

## Q. What is PROSPECT?

PROSPECT (**PRO**spective study for **Sym**Ptomatic relief of **Essential** tremor with **Cala** Therapy) is the largest therapeutic study ever conducted in ET.

## 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 show 62% of patients improved in tremor severity from severe/moderate to mild/slight according to the TETRAS rating scale, and 68% of patients improved in tremor severity from severe/moderate to mild according to ADL rating scale (baseline vs. three months). The average symptom reduction lasted 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.

## Cala Health® Business

## Q. What is Cala Health's fundraising total?

Total fundraising to date is \$84 million. Cala Health completed a \$50 million Series C financing in May 2019. New investors in the Series C financing include Novartis, Baird Capital, LifeSci Venture Partners, TriVentures, and others. All existing investors participated in the round, including Johnson & Johnson Innovation –JJDC, Inc. (JJDC), Lux Capital, Lightstone Ventures, Action Potential Venture Capital, dRx Capital, and GV.

## Q. Does Cala Health work with academic institutions?

Cala Health has a licensing agreement and ongoing collaboration with Partners Healthcare Innovation and its affiliate, Massachusetts General Hospital (MGH).

The technology licensed by Cala Health was developed from research on transcutaneous vagus nerve stimulation (tVNS) and Respiratory-Gated Vagal Afferent Nerve Stimulation (RAVANS) in the MGH research lab of Vitaly Napadow, Ph.D., LicAc. The technology stems from years of research at MGH on the connection between the brain and cardiac function. It will help accelerate the development of wearable neuromodulation therapies in chronic disease. As part of this agreement, the MGH researchers who created the technology will work with Cala Health as scientific advisors in development to further accelerate the investigation of non-invasive therapies.

## Q. How is Cala Health responding to the global pandemic?

During this unprecedented time, Cala Health is working diligently to follow all protocols set by our health and government leaders. As an Essential Employer we are processing new and existing prescriptions, providing Cala Trio users with online resources/ phone training, and supporting physicians. Living independently at home is very challenging for people with essential tremor, particularly those of the hand. Fortunately, Cala Trio is easy to prescribe with a telemedicine consultation and does not require any in-office appointments, mitigating potential COVID-19 exposure for patients and prescribers.



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