Neuralink Clinical Trial

PRIME Study: Precise Robotically Implanted Brain-Computer Interface

We invite you to participate in the PRIME Study – a ground-breaking investigational medical device clinical trial for our first brain-computer interface.

If you have quadriplegia and are interested in exploring new ways of controlling your computer, you may qualify.

What are brain-computer interfaces?

Brain-computer interfaces (BCIs) are systems that decode intended movement signals from brain activity to control external devices such as computers.

What is the purpose of this study?

This is a first-in-human study with the purpose of evaluating the safety and initial effectiveness of the N1 Implant (a BCI implant), the R1 Robot (a surgical robot), and N1 User App (BCI software) in enabling individuals with paralysis to control external devices.

The devices used in this study are investigational, and not for sale.

What does the study involve?

During the study, the R1 Robot will be used to surgically place the N1 Implant in a region of the brain that controls movement intention.

Participants will be asked to use the N1 Implant and N1 User App to control a computer and provide feedback about the system.

Compensation

You will be compensated for study-related costs (such as travel expenses to and from the study site).

Our Devices

N1 Implant

Once surgically placed, the N1 Implant is cosmetically invisible. It records and transmits brain activity with the goal of enabling you to control a computer.

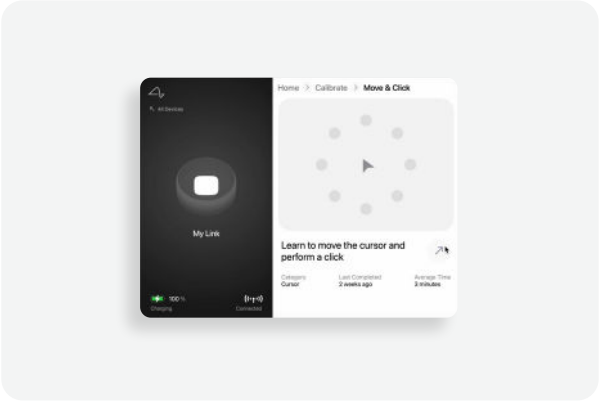
The N1 Implant records neural activity through 1024 electrodes distributed across 64 threads, each thinner than a human hair.

R1 Robot

The R1 Robot has been designed to reliably and efficiently insert the threads of the N1 Implant into the appropriate region of the brain.

N1 User App

Neuralink has created an app that decodes movement intention from brain signals recorded by the N1 Implant, allowing you to control a computer with your thoughts.



Eligibility

We are looking for individuals who:

- Have quadriplegia (limited function in all 4 limbs) due to spinal cord injury or amyotrophic lateral sclerosis (ALS) and are at least 1-year post-injury (without improvement)
- Are at least 22 years old
- Have a consistent and reliable caregiver

Regrettably, we can't accept individuals who:

- Have an active implanted device (pacemaker, deep brain stimulator (DBS), etc.)
- Have a history of seizures
- Require MRIs for an ongoing medical condition
- Are receiving transcranial magnetic stimulation (TMS) treatment

Time Commitment

The study will take approximately 6 years to complete. During the study, you will have regular follow-ups with our team of experts to monitor your progress and ensure the Neuralink BCI continues to work as intended.

Primary Study

The Primary Study involves a combination of 9 at-home and in-person clinic visits and takes place over approximately 18 months.

BCI Research Sessions

You will be asked to participate in BCI research sessions for the duration of the study, with a minimum commitment of 2 sessions per week, for 1 hour per session.

Long-term Follow-up

The long-term follow-up begins immediately after completion of the Primary Study and takes place over 5 years, with a total of 20 visits.

Get in touch

Thank you for considering the PRIME Study! We look forward to hearing from you.

Let us know if you're interested in our current and future trials by visiting neuralink.com/patient-registry or scanning the QR code below.

neuralink.com/patient-registry