

A research study of a brain–computer interface communication device for people with ALS

Cognixion Corporation is conducting a research study comparing a wearable brain–computer interface (BCI) communication device with the eye-tracking communication devices people with ALS already use. The study runs at home over about 12 weeks. Approximately 30 people across the United States will take part.

WHO MAY BE ABLE TO TAKE PART

- Adults **18 years or older** with a diagnosis of **ALS**
- Speech is significantly affected — difficult for others to understand, or no longer able to speak
- Currently use a **Tobii Dynavox or Smartbox eye-tracking communication device** (for at least 30 days) or evaluating using an eye tracking device.
- Have a **caregiver** who can be trained and present for each session with the study device
- Can keep the eyes open for at least 30 minutes at a time (with normal blinking).
- Can see a display screen and smart glasses display clearly with or without corrective lenses.
- Can reliably answer **yes or no** by some means other than the study device (e.g. nodding, eye blink, pupil motion, etc.)
- Able to read and understand English

WHO CANNOT TAKE PART

- History of **seizures, epilepsy, or sensitivity to flashing lights**
- Certain vision conditions affecting the field of view, a history of vertigo or balance disorders, or a scalp condition that would make sensor placement unsafe
- Other certain vision condition
- Currently enrolled in another communication-device or BCI research study

The study team will review the full list of requirements with you.

WHAT TAKING PART INVOLVES

- **About 12 weeks** of regular practice, with the option to continue longer
- **3 to 5 sessions per week**, about 1 hour each, in your own home
- Trying **three communication options**: your own eye-tracking device, a head-worn version of the study device, and a screen-based version
- For some sessions you choose which option to use — **that choice is part of what is being studied**
- A study team member checks in **weekly by phone or video**, and visits in person about once a month
- A short 10-minute ALS questionnaire every 4 weeks
- Equipment is delivered and set up in your home, and your caregiver is trained by the study team

COST AND PAYMENT

- **Participants** may be allowed to keep study equipment at end of study.
- **No cost** to take part. All equipment and supplies are provided.
- **No payment** is offered for taking part.

Please read before you get in touch. This is a research study, not medical treatment. The Cognixion ONE device is an **investigational research device**. It is not approved or cleared by the U.S. Food and Drug Administration for any medical use, and there is no guarantee that anyone taking part will benefit from it.

There are risks, including discomfort from wearing the device, skin irritation, and fatigue. The study team will go through all of the risks, and the full consent form, with you and your caregiver before you decide anything.

Taking part is **entirely voluntary**. You may decide not to join, or stop at any time, without affecting your medical care or your relationship with the organization that gave you this flyer. Your regular ALS care continues unchanged.

TO FIND OUT MORE

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Cognixion study team

Contacting the study team does **not** commit you to anything. A short, no-obligation phone conversation is the first step, to see whether the study might be a fit.

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Questions about your rights as a research participant? Contact Sabai IRB, the independent review board that oversees this study, at (888) 265-5766 or irbteam@sabaiglobal.com.

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