

Participating in research is a choice

Joining a research study is an important personal decision. Before you join, researchers will talk with you about the goals of the study, and possible risks and benefits. They will also explain the rules they follow to protect your safety and privacy. Ask for help if you don't understand something or have questions.

You should never feel rushed or pressured to make a decision. Being part of a research study is completely voluntary – it's your choice.

After you understand the study and you decide to take part, you will be asked to sign a document called an "informed consent form." You can change your mind at any time, for any reason, even after you sign.

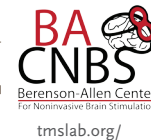


This material is the work of the New England Research Subject Advocacy Group, with contributions from the affiliated universities and academic healthcare centers of member institutions. For more information see: <http://catalyst.harvard.edu/regulatory/language.pdf>.

Questions to ask

You have the right to ask questions about a research study before you decide whether to take part in it. Below is a list of questions you might want to ask before you take part in a tES research study.

- > What type of tES will I receive?
- > Why is this research being done?
 - Where will the electrodes be placed and how will they be held in place?
- > What area of the brain is being stimulated?
- > How much current will I receive?
- > How long will my tES session last?
- > How many sessions does this study have?
- > How should I get ready for a study visit?
- > What are the risks and side effects of tES?
- > Will this procedure have short-term or long-term effects?
- > Will I learn the results of my tES procedure?
- > Will the tES results become part of my medical record?
- > Will my insurance company pay for tES? Will I have to pay anything?
- > What if I decide to leave the study early?
- > Has the FDA approved the procedure in this study?
- > Does this study involve other procedures?



Questions? Call us at



TRANSCRANIAL ELECTRICAL STIMULATION FOR RESEARCH



Participating in research is your choice.
Be informed. Ask questions. Get answers.

Transcranial electrical stimulation is a way to stimulate the brain. It is also called tES. Here's how it works: a researcher puts small discs or sponges called "electrodes" over your head. Then, the electrodes placed on the outside of your head send a weak electric current to your brain.

This brochure contains general information for educational purposes and is not intended to provide medical advice. Talk with your own doctor or the research team for advice about your personal situation and health concerns.

Why do researchers use tES?

Researchers use tES to learn more about how the brain works. For example, tES helps researchers learn how brain activity is related to thoughts and behavior. They also use tES to understand certain diseases and symptoms.

Some of these diseases and conditions include:

- > Parkinson's disease
- > Depression
- > Fibromyalgia
- > Schizophrenia
- > Epilepsy
- > Stroke
- > Chronic pain
- > Traumatic brain injury

Some researchers are studying the use of tES for the treatment of brain diseases. Before tES can be approved to treat or diagnose an illness, the US Food and Drug Administration (FDA) must give approval. The FDA has not yet approved any tES device for treating any disease or condition.

The FDA has approved some tES products that are sold directly to consumers not for research purposes. However, these are not for medical use. For more information about the FDA and their review of tES devices, please visit [FDA.gov](https://www.fda.gov).

How long does tES take?

Most tES sessions last about 30 minutes. Your research team will give you an estimate of how long your tES session will take.

How is tES done?

You sit in a chair and a member of the research team will place electrodes on your head. The electrodes will be held in place with a band or cap. The electrodes might be small discs or damp sponges. They are connected with wires to a box that creates a weak electric current. This box might be on a table next to you or attached to the cap or band.

A weak current travels through the wires to the electrodes on your head. It might feel like a slight sting or itch when it is turned on. A small amount of the weak electric current goes into your brain and can affect brain activity.

Make sure you understand what to expect before, during, and after tES. Talk with the research staff so that you understand how to prepare for tES.

What are the different types of tES?

The researcher will explain what type you will get.

The three main types of tES are:

- > **Transcranial alternating current stimulation, or tACS.** This type of tES uses an electrical current that regularly changes direction at a set rate. Researchers believe this may change the rhythm of brain activity.
- > **Transcranial random noise stimulation, or tRNS.** This type of tES uses an electric current that changes direction randomly and often. Researchers believe this may make certain brain activities stand out more.
- > **Transcranial direct current stimulation, or tDCS.** This is the type of tES that researchers have studied the most. It uses an electrical current that goes into the brain in one direction.

What are the risks of tES in a research study?

tES is usually considered safe and relatively painless. During the stimulation, you might feel some tingling, itching, or burning under the electrodes. This usually goes away quickly. After tES, your skin might be red or irritated, but this also goes away quickly. You should always tell the research staff if something is uncomfortable before, during, and after the procedure.

There might be other tES side effects that researchers do not yet know about.

Any research study may involve some risk. The informed consent form for your study will describe any specific risks. Make sure you understand the risks of tES and the rest of the study before you agree to take part.