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.

Questions to ask

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

- > Why is this research being done?
- > Is this TMS procedure only for the research study? Or is it also part of my regular medical care?
- > Does this study involve other procedures?
- > What area of my brain is being stimulated?
- > How many times will I have TMS in the study?
- > How should I get ready for my study visit?
- > What are the risks and side effects of having TMS?
- > Will this procedure cause short-term and/or longterm side effects?
- > Will I learn the results of my TMS procedure?
- > Will the results become part of my medical records?
- > Will my insurance company pay for the TMS procedure? Will I have to pay anything?
- > What happens if I decide to leave the study early?



Health Research

TRANSCRANIAL MAGNETIC STIMULATION FOR RESEARCH



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

Transcranial magnetic stimulation is a way to stimulate the brain. It is also called TMS. Here's how it works: a researcher holds a small device called a "coil" on your head. This creates magnetic energy. The magnetic energy enters your brain through the coil, creating an electric current. The electric current stimulates your brain cells.

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? Call us at

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 TMS?

Researchers use TMS to learn how the brain works. For example, TMS helps researchers learn how brain activity controls behavior and how the brain is organized. Researchers also use TMS to understand how brain activity is different in patients with different diseases or conditions. Some of these diseases and conditions include:

- > Parkinson's disease
- > Alzheimer's disease
- > Epilepsy
- > Schizophrenia
- > Autism
- > Traumatic brain injury
- > Chronic pain
- > Stroke

Before TMS can be used to treat or diagnose an illness, the US Food and Drug Administration (FDA) must approve the device for this purpose. For example, the FDA has approved several TMS devices for treatment of major depression and migraine. For more information about the FDA and their review of TMS devices, please visit *FDA.gov*.

How much time does TMS take?

Depending on the research, the duration of a TMS session varies from a few minutes to several hours. For example, single pulses of TMS may be given for just a few minutes. Other times, repetitive pulses of TMS may be given continuously for up to 30 minutes. Your research team will give you an estimate of how long each appointment will take and how many they would like you to participate in.

How is TMS done?

You might wear a swim cap or a headband as the researcher holds the TMS "coil" on your head. Then, a researcher will start the stimulation. This creates a magnetic energy called a "pulse". The pulse creates a current that stimulates a small part of your brain. You will know when the coil is on because you will hear a clicking noise and might feel tapping on your head. The researchers might also use electrodes (small discs with wires) to measure the effects of the stimulation.

TMS can be applied one pulse at a time or as a series of pulses. The research staff will explain the amount of TMS pulses they are using. Make sure you understand what to expect before, during, and after the procedure. Talk with the research staff so that you understand how to prepare for the TMS procedure.

What are the risks of TMS?

TMS is usually considered safe and relatively painless. A mild headache is the most common side effect. This can happen during TMS or just after it. Depending on where researchers put the coil, muscles in your face, head, neck, or hand might twitch, or move slightly. This can be uncomfortable. The clicking noise from the TMS could affect your hearing for a short time. Researchers will give you earplugs to help protect your hearing. There is a small risk of having a seizure with TMS, but this is very rare. There might be other TMS side effects researchers do not yet know about.

Any research study may involve some risks. The informed consent form for your research study will tell you any specific risks. Discuss these details with the research team. Make sure you understand the risks of TMS and the rest of the research study before you decide to take part.

