Questions to ask

You have the right to ask questions about a clinical trial before you decide whether to participate. Below is a list of some questions you might want to ask before you agree to take part in a clinical trial:

- What is the purpose of this study?
- Is the acupuncture provider licensed and trained?
- Will new, sterile needles be used?
- What makes me eligible to participate in the clinical trial?
- What will I be asked to do as part of the clinical trial?
- How many sessions will there be and how long will each session take?
- What are the potential benefits and risks if I participate?
- What are my alternatives to participating?
- Will I be paid for participating in the clinical trial?
- If I develop any problems from the trial, will the study pay for my medical care?

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 that you need to make a decision right away. Being part of a research study is completely your choice. It is voluntary. And your doctors will continue to care for you whether or not you are in a study.

After you understand the study and you decide whether you will 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 the form.

Where can I find out more about clinical trials?

Your healthcare provider or the research team may be able to help you find more information about clinical trials. You can also look up trials on ClinicalTrials.gov, a database of clinical trials that is managed by the National Institutes of Health (NIH).

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What is acupuncture?

Acupuncture is an ancient form of therapy that stimulates specific points on the body using tiny needles that go through the skin. It is used most commonly to treat pain. The needles are tiny and sterile—and should be used only once. Trained therapists (called acupuncturists) should perform the technique which, when done properly, is safe. Often an acupuncturist holds a license to perform acupuncture. Be sure to ask about it.

What happens during an acupuncture session?

You should wear loose-fitting, casual clothes. You can eat and drink beforehand. Prior to your first session, you will fill out a form about your symptoms and your health. The therapist will need access to various points on your body, depending on the reason for your visit. You will lie on a table or be seated.

The therapist will clean the skin, then gently insert tiny, thin needles at various points just through the skin. The needles are often turned by hand or stimulated by electricity. Some people feel tingling, numbness, warmth, or a “heavy” feeling, and rarely some dull pain. You will relax for 15-30 minutes with the needles in place.

The therapist will return to remove the needles. Removal is painless. You will be asked some questions. You might feel relaxed or energetic for a few hours after a session. Acupuncture can vary among different practitioners and in different countries. You may need several treatments before you know if the therapy is improving your condition or not. Ask questions. Talk to your therapist. They are there for you.

Why are researchers using acupuncture?

Acupuncture does not work for everyone, and it’s not clear exactly how it works. Researchers are trying to understand how acupuncture helps some people and not others, and for what conditions.

Sometimes researchers use an inactive procedure (blunt needles that do not go through the skin but look like they do, or needles placed on other parts of your body) to test whether a response is related to the acupuncture or something else. This is called a “placebo,” or “sham” procedure, and is safe. You should ask the researcher if the study involves a placebo procedure.

Who can participate in an acupuncture study?

The researchers will decide whether you could be a good fit for a study. For example, if you have a severe bleeding problem, have a pacemaker, or are pregnant, an acupuncture study might not be good for you.

You should always tell your doctor or healthcare provider if you have any health problems or other problems. You should not wait for acupuncture to work to discuss your health or problems with your healthcare provider.

What are the risks and benefits of participating in an acupuncture study?

Each clinical trial is different, but some potential benefits and risks might include:

**Benefits:**

Acupuncture may treat pain, nausea, headache, anxiety, sleeping issues, and other conditions. You may feel better after the sessions, or you may not.

**Risks:**

Rarely, acupuncture can worsen your symptoms. Some bleeding at the site of the needle may occur. You may feel tired or sore, or have some bruising and/or some muscle soreness after your treatment. Some people get dizzy or lightheaded. Very rarely, a needle can prick a lung or a vital organ and cause nerve or other serious damage, and even death. It is important that a qualified and trained (and preferably, licensed) provider of acupuncture perform the treatments using sterile needles. If the needles are not sterile, there is a risk of infection, which can become serious.

**Remember:** Tell your doctor or healthcare provider if you have a health or other problem. Do not delay.

Any study may involve risks; the informed consent form for your research study will tell you about any specific risks. Discuss these details with the research team. Make sure you understand both the risks and the study itself before you decide to take part in the clinical trial.