You may be assigned (or randomized) to a specific study group. This means that you might receive the care you would normally receive (called standard care), or the experimental treatment (the treatment or medication being studied). If the study is blinded, or masked, you will not know which group you are in. Blinded studies are performed so that the patients' and/or the doctors' expectations about the experimental treatment cannot influence the outcome.

What questions should I ask?

If you decide to join a clinical trial, the next step is to contact the study research staff and ask your questions. You might want to bring a friend when you meet with the research staff or write down your questions ahead of time. Some sample questions you might ask are:

- What is the purpose of the study? Why does the research team think the treatment or medication will work?
- How long will the study last?
- Where is the study site? How often will I need to go there?
- Will I have to pay anything to participate in the study?
- What kinds of therapies, procedures, and/or tests will I have during the trial?
- What are the risks, side effects, and benefits of the study compared with standard treatment?
- Will I be reimbursed for any expenses?
- Will I be able to take my regular medications during the trial?
- Can anyone find out that I am participating in a study?
- Can I talk to other people in the study?
- Who will provide my medical care after the study ends?

Where can I go for more information?

For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at ***www.drugabuse.gov.***

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government sponsored clinical trials. You may log on to ***www.Clinicaltrials.gov*** to learn about ongoing or new trials for all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

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6001 Executive Boulevard
Room 4234, MSC 9557
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NIDA NATIONAL INSTITUTE ON DRUG ABUSE

National Drug Abuse Treatment
Clinical Trials Network

What are Clinical Trials?

Should I Participate?

National Institutes of Health
U.S. Department of Health and Human Services

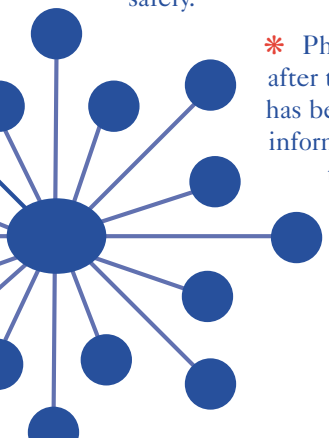
What are clinical trials?

A clinical trial is a research study to answer specific questions about new treatments or vaccines for a health-related condition, such as drug addiction. Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Clinical trials are also used to determine the best way to use a standard treatment.

All clinical trials are based on a set of rules called a protocol, which describes what types of people may participate, the schedule and doses of the treatment, and the length of the study.

Clinical trials for medications proceed through four phases:

- In Phase I clinical trials, researchers test a new medication or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- In Phase II clinical trials, the study medication or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
- In Phase III studies, the study medication or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- Phase IV studies are done after the medication or treatment has been marketed. They collect information about the effect of the treatment in various populations and side effects associated with long-term use.



Stages of Research Using Behavioral Therapies

Behavioral therapies including drug counseling, psychotherapy, family therapy, cognitive-behavior therapy, and motivation therapies are the most common forms of treatment used for drug addiction. The three stages of behavioral research are:

- Stage I, This includes the early phases of development and pilot testing of behavioral interventions.
- Stage II, This consists of efficacy testing of promising therapies, and can be aimed at determining the mechanism of action of behavioral therapies.
- Stage III, This research consists of studies to test if and how behavioral therapies can be transported to community settings.

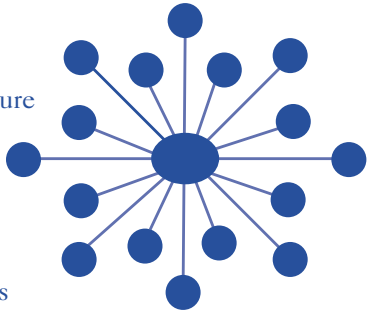
Should I participate?

Choosing to participate in a clinical trial is an important personal decision. It is often helpful to talk to your health care provider, family members, or friends about deciding to join a trial.

Why clinical trials are important. One of the most important reasons for participating in a clinical trial is the knowledge that you are contributing to the development of new treatments for people who suffer from the same condition you have.

How you can benefit. By participating in a clinical trial, you can 1) have an active role in your treatment, 2) gain access to new treatments that are not available to the public, and 3) obtain expert medical care at leading health care facilities during the trial. On the other hand, the treatment you receive may have side effects, it may not be effective for you, and it may require a lot of your time. You need to weigh these risks and benefits.

How you are protected. The government has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the United States must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. The IRB members are neutral reviewers who ensure that the study is conducted fairly.



In addition, if you are considering joining a clinical trial, the research staff will give you informed consent documents which describe the study, including the nature of the study, the risks involved, and what may happen to you during the study. The informed consent also explains that you have a right to leave the study at any time. You may want to take these forms home and discuss them with your family or health care provider. You should feel free to ask the research team any questions before, during, or after the study. You may leave the clinical trial at any time. However, let the research team know why you are leaving because it may impact on others in the study.

What can I expect?

Before you join a clinical trial, you must qualify for the study; this decision is based on factors such as age, type of dependence, medical history, and current medical condition. These criteria help ensure that researchers will be able to answer the questions they plan to study.

At the beginning of your participation, a team of researchers and health care providers will check your health and give you instructions about your responsibilities. They will also monitor you during the study and stay in touch with you after the study. Some trials involve more tests and visits than you would normally have for your condition. Your cooperation is needed in order for you to complete the study safely.