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What Are Clinical Trials and Studies?

Español

By participating in clinical research, you can help scientists develop new medications and other strategies to treat and prevent disease. Many effective treatments that are used today, such as chemotherapy, cholesterol-lowering drugs, vaccines, and cognitive-behavioral therapy, would not exist without research participants. Whether you're healthy or have a medical condition, people of all ages and backgrounds can participate in clinical trials. This article can help you learn more about clinical research, why people choose to participate, and how to get involved in a study.

Mr. Jackson's story

Mr. Jackson is 73 years old and was just diagnosed with **Alzheimer's disease**. He is worried about how it will affect his daily life. Will he forget to take his medicine? Will he forget his favorite memories, like the births of his children or hiking the Appalachian Trail? When Mr. Jackson talked to his doctor about his concerns, she told him about a clinical trial that is testing a possible new Alzheimer's treatment. But Mr. Jackson has concerns about clinical trials. He does not want to feel like a lab rat or take the chance of getting a treatment that may not work or could make him feel worse. The doctor explained that there are both risks and benefits to being part of a clinical trial, and she talked with Mr. Jackson about research studies — what they are, how they work, and why they need volunteers. This information helped Mr. Jackson feel better about clinical trials. He plans to learn more about how to participate.

What is clinical research?

Clinical research is the study of health and illness in people. There are two main types of clinical research: observational studies and clinical trials.

Observational studies monitor people in normal settings. Researchers gather information from people and compare changes over time. For example, researchers may ask a group of older adults about their exercise habits and provide monthly memory tests for a year to learn how physical activity is associated with cognitive health. Observational studies do not test a medical intervention, such as a drug or device, but may help identify new treatments or prevention strategies to test in clinical trials.

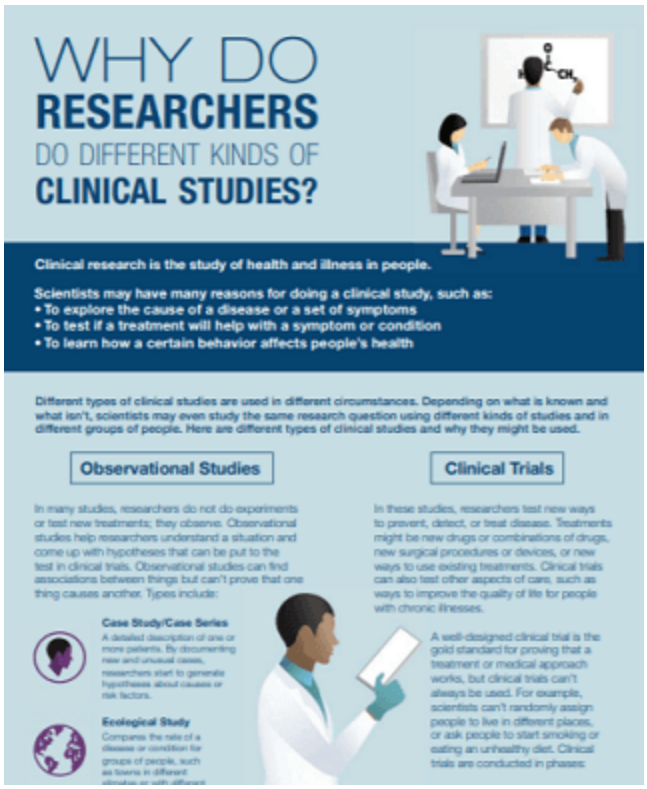
Clinical trials are research studies that test a medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or

medical device (for example, a pacemaker), is safe and effective in people. Often, a clinical trial is designed to learn if a new treatment is more effective or has less harmful side effects than existing treatments.

Other aims of clinical research include:

- Testing ways to diagnose a disease early, sometimes before there are symptoms
- Finding approaches to prevent a health problem, including in people who are healthy but at increased risk of developing a disease
- Improving quality of life for people living with a life-threatening disease or chronic health problem
- Studying the role of caregivers or support groups

Learn more about clinical research from MedlinePlus and ClinicalTrials.gov.



Read and share this infographic (PDF, 317K) to learn why researchers do different kinds of clinical studies.

What is a Clinical Trial? (English)

Why participate in a clinical trial?

People volunteer for clinical trials and studies for a variety of reasons, including:

- They want to contribute to discovering health information that may help others in the future.
- Participating in research helps them feel like they are playing a more active role in their health.
- The treatments they have tried for their health problem did not work or there is no treatment for their health problem.

Whatever the motivation, when you choose to participate in a clinical trial, you become a partner in scientific discovery. Participating in research can help future generations lead healthier lives. Major medical breakthroughs could not happen without the generosity of clinical trial participants — young and old, healthy, or diagnosed with a disease.

Read and share this infographic to learn more about how clinical research might be right for you.

Where can I find a clinical trial?

Looking for clinical trials related to aging and age-related health conditions? Talk to your health care provider and use online resources to:

- Search for a clinical trial
- Look for clinical trials on Alzheimer's, other dementias, and caregiving
- Find a registry for a particular diagnosis or condition
- Explore clinical trials and studies supported by NIA

After you find one or more studies that you are interested in, the next step is for you or your doctor to contact the study research staff and ask questions. You can usually find contact information in the description of the study.

Let your health care provider know if you are thinking about joining a clinical trial. Your provider may want to talk to the research team to make sure the study is safe for you and to help coordinate your care.

Joining a clinical trial is a personal decision with potential benefits and some risks. Learn what happens in a clinical trial and how participant safety is protected. Read and listen to testimonials from people who decided to participate in

research.

What happens in a clinical trial or study?

Here's what typically happens in a clinical trial or study:

1. Research staff explain the trial or study in detail, answer your questions, and gather more information about you.
2. Once you agree to participate, you sign an informed consent form indicating your understanding about what to expect as a participant and the various outcomes that could occur.
3. You are screened to make sure you qualify for the trial or study.
4. If accepted into the trial, you schedule a first visit, which is called the "baseline" visit. The researchers conduct cognitive and/or physical tests during this visit.
5. For some trials testing an intervention, you are assigned by chance (randomly) to a treatment group or a control group . The treatment group will get the intervention being tested, and the control group will not.
6. You follow the trial procedures and report any issues or concerns to researchers.
7. You may visit the research site at regularly scheduled times for new cognitive, physical, or other evaluations and discussions with staff. During these visits, the research team collects data and monitors your safety and well-being.
8. You continue to see your regular physician(s) for usual health care throughout the study.

> ### How do researchers decide which interventions are safe to test in people?
>
> Before a clinical trial is designed and launched, scientists perform laboratory tests and often conduct studies in animals to test a potential intervention's safety and effectiveness. If these studies show favorable results, the U.S. Food and Drug Administration (FDA) **approves the intervention** to be tested in humans. Learn more about how the **safety of clinical trial participants** is protected.

What happens when a clinical trial or study ends?

Once a clinical trial or study ends, the researchers analyze the data to determine what the findings mean and to plan the next steps. As a participant, you should be provided information before the study starts about how long it will last, whether you will continue receiving the treatment after the trial ends (if applicable), and how the results of the research will be shared. If you have specific questions about what will happen when the trial or study ends, ask the research coordinator or staff.

What are the different phases of clinical trials?

Clinical trials of drugs and medical devices advance through several phases to test safety, determine effectiveness, and identify any side effects. The FDA typically requires Phase 1, 2, and 3 trials to be conducted to determine if the drug or device can be approved for further use. If researchers find the intervention to be safe and effective after the first three phases, the FDA approves it for clinical use and continues to monitor its effects.

Each phase has a different purpose:

- A **Phase 1** trial tests an experimental drug or device on a small group of people (around 20 to 80) to judge its safety, including any side effects, and to test the amount (dosage).
- A **Phase 2** trial includes more people (around 100 to 300) to help determine whether a drug is effective. This phase aims to obtain preliminary data on whether the drug or device works in people who have a certain disease or condition. These trials also continue to examine safety, including short-term side effects.
- A **Phase 3** trial gathers additional information from several hundred to a few thousand people about safety and effectiveness, studying different populations and different dosages, and comparing the intervention with other drugs or treatment approaches. If the FDA agrees that the trial results support the intervention's use for a particular health condition, it will approve the experimental drug or device.
- A **Phase 4** trial takes place after the FDA approves the drug or device. The treatment's effectiveness and safety are monitored in large, diverse populations. Sometimes, side effects may not become clear until more people have used the drug or device over a longer period of time.

Clinical trials that test a behavior change, rather than a drug or medical device, advance through similar steps, but behavioral interventions are not regulated by the FDA. Learn more about clinical trials, including the types of trials and the four phases.

Questions to ask before participating in clinical research

Choosing to participate in research is an important personal decision. If you are considering joining a trial or study, get answers to your questions and know your options before you decide. Here are questions you might ask the research team when thinking about participating.

About the study +

Medical care +

Costs and reimbursement +

After the study ends +

How do researchers decide who will participate?

Clinical trials often test how a medical intervention affects people with a certain disease, family history, or lifestyle. Because of this focus, not everyone meets the criteria to participate in every trial. After you consent to participate, the research staff will ask questions and perform tests to see if you are eligible for the trial. The screening may involve blood and other laboratory tests, thinking and memory tests, and a physical examination.

To be eligible to participate, you may need to have certain characteristics, called inclusion criteria. For example, a clinical trial may need participants to have a certain stage of disease, version of a gene, or family history. Some trials require that participants have a study partner who can accompany them to clinic visits.

Participants with certain characteristics may not be allowed to participate in some trials. These characteristics are called exclusion criteria. They include factors such as specific health conditions or medications that could interfere with the treatment being tested.

Many volunteers must be screened to find enough people who are eligible for a trial or study.

Generally, you can participate in only one clinical trial at a time, although this is not necessarily the case for observational studies. Different trials have different criteria, so being excluded from one trial does not necessarily mean you will be excluded from another.

Volunteering for Clinical Trials as a Healthy Participant - Bob's Story

Clinical research needs participants with diverse backgrounds

When research only includes people with similar backgrounds, the findings may not apply to or benefit a broader population. The results of clinical trials and studies with diverse participants may apply to more people. That's why research benefits from having participants of different ages, sexes, races, and ethnicities.

Researchers need older adults to participate in clinical research so that scientists can learn more about how new drugs, tests, and other interventions will work for them. Many older adults have health needs that are different from those of younger people. For example, as people age, their bodies may react differently to certain drugs. Older adults may need different dosages of a drug to have the intended result. Also, some drugs may have different side effects in older people than in younger individuals. Having older adults enrolled in clinical trials and studies helps researchers get the information they need to develop the right treatments for this age group.

Read and share this infographic about the types of volunteers needed for dementia research.

Why These Four People Participate in Alzheimer's Research

Researchers know that it may be challenging for some older adults to join a clinical trial or study. For example, if you have multiple health problems, can you participate in research that is looking at only one condition? If you are frail or have a disability, will you be strong enough to participate? If you no longer drive, how can you get to the research site? Talk to the research coordinator or staff about your concerns. The research team may have already thought about some of the potential obstacles and have a plan to make it easier for you to participate.

Read more about diversity in clinical trials.

You may also be interested in

- Learning more about the benefits, risks, and safety of clinical research
- Finding out about participating in Alzheimer's disease research
- Downloading or sharing an infographic with the benefits of participating in clinical research

For more information about clinical trials

Alzheimers.gov
www.alzheimers.gov
Explore the Alzheimers.gov website for information and resources on Alzheimer's and related dementias from across the federal government.

Clinical Research Trials and You
National Institutes of Health
www.nih.gov/health-information/nih-clinical-research-trials-you

ClinicalTrials.gov
www.clinicaltrials.gov

This content is provided by the NIH National Institute on Aging (NIA). NIA scientists and other experts review this content to ensure it is accurate and up to date.

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