Clinical Trials and Older Adults

How to decide if a trial is right for you

From the National Institute on Aging

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By joining clinical trials, older adults may help doctors find new treatments.

What's inside

Clinical trials have led to all the medicines and treatments we use today. Doctors need older adults to join their clinical trials so they can learn more about how new treatments will work for older people. Use this booklet to help you decide if taking part in a clinical trial is right for you, a friend, or a family member.

This booklet will help you learn:

- What a clinical trial is
- Reasons why people take part in a clinical trial
- How to find a clinical trial
- Benefits and risks of a clinical trial

Tips about using this booklet

Use the Table of Contents to help you find things quickly. Some medical terms, such as **placebo**, are in bold. You can find how to say these words and what they mean in the "Words to know" section on page 18.

James's story

James is 73 years old and just found out that he has Alzheimer's disease. He and his wife, Alice, are worried about how it will change their daily lives. Will he forget to take his medicine? Will he forget his favorite memories or people he knows? When James and Alice talked to his doctor about their concerns, she told them about a clinical trial that is testing a possible new treatment for Alzheimer's. Alice will be part of the trial, too, as James's study partner.

What is a clinical trial?

Like James, you might have heard of clinical trials but may not be sure what they are or if you want to join one. This booklet gives you information about clinical trials and can help you decide if taking part in one is right for you.

A clinical trial is a type of research study that involves people. Most clinical trials test a new treatment for a health problem, like a new drug, diet, or medical device (for example, a pacemaker for your heart). Clinical trials help doctors learn if a new treatment is better, the same, or worse than normal care.

Other clinical trials test ways to prevent a disease or find it early. Most medicines that people use today have been tested in clinical trials.

Before the Federal Government can approve a medicine or other treatment for people, it must be tested to make sure it is safe and it works. Sometimes, treatments are tested in animals first. Then, doctors run clinical trials with people to find out what happens when they get the new treatment.

In many clinical trials, doctors compare two groups of people. One group of volunteers will get the new treatment being tested. The other group of volunteers will get a **placebo** (a pill or other treatment with no medicine in it). A computer decides which group a volunteer will be in. This is called **randomization**. In many trials, no one—not even your doctor—knows who gets the treatment or the placebo.

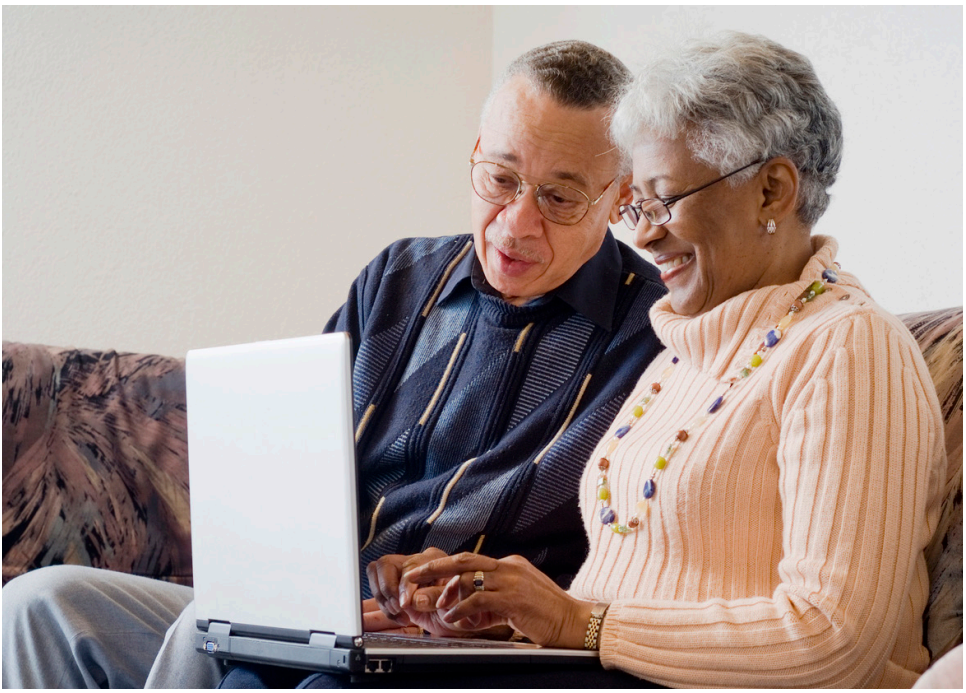
Ana's story

Ana is 80 years old. She has been feeling weak and falling a lot. She tried different medicines, but they did not work well. She asked her doctor if there were any new treatments being tested in a clinical trial. Together, they found a clinical trial that was right for her.

Being in a clinical trial means Ana gets to talk with medical experts and learn more about her condition. She does not know if she is getting the new treatment or the placebo. But Ana is glad she gets medical care and has regular check-ups for her health condition. Plus, she feels good knowing she is doing something that might help her children and grandchildren in the future.

Why consider a clinical trial?

There are many reasons why people choose to join a clinical trial. Some join a trial because there is no other treatment for their health problem or because the treatments they tried did not work. By being part of a clinical trial, people may help doctors find new treatments. Some people who are healthy may also join studies to help find ways to prevent a disease, such as one that may be common in their family.



Healthy people may join a clinical trial to help find ways to prevent a disease.

Where can you find a clinical trial?

There are many ways to find a clinical trial that might be right for you. You can:

- Ask your doctor to help you find trials in your area.
- Sign up for a registry or a matching service to connect you with trials in your area.
- Search the National Institutes of Health website www.ClinicalTrials.gov.

Support groups and websites that focus on a specific health problem sometimes list clinical trials. You may also see ads for trials in your area in the newspaper or on TV.

You can find clinical trials on the National Institutes of Health website at www.ClinicalTrials.gov.

What happens in a clinical trial?

Once you find a trial you are interested in, talk with your regular doctor. Next, contact the study team that runs the trial in your area and talk to the **study coordinator**. You can usually find this contact information in the details about the study. The study coordinator will ask a few questions to see if you match the type of person they are looking for. He or she will ask about your age, sex, type and stage of disease, function, and other health problems.

If you match, you will be invited to visit the study site to learn more. During this **informed consent** process, the study team will explain the purpose of the study and the possible risks and benefits to you if you choose to join. You will learn everything that will happen during the study and

A study coordinator can answer your questions about a clinical trial. You will sign a consent form if you decide to join.

what you will need to do, such as how many times you will visit the study site and any tests you will take. The study team will answer all your questions to help you decide whether or not you want to join the trial.

If you decide to join, you will sign a consent form. It means that you understand what will happen during the study and that you want to be part of it. Even after you sign up for the study, you can choose to stop participating at any time.

While participating in the study, you will visit the study site regularly to get tests and make sure you are doing well.

Make sure to tell your regular doctor if you are thinking about joining a clinical trial. He or she may want to talk to the study team to make sure the trial is safe for you and to coordinate your care while you are in the trial.

Once you find a clinical trial you want to join, talk with your doctor.

Questions to ask before participating in a clinical trial

Here are some questions you may have about joining a clinical trial. Write down your questions and bring the list when you first meet with the research team.

1. What is this study trying to find out?
2. What will I have to do?
3. What treatment or tests will I have? Will they hurt? Can I get the treatment after I finish the study?
4. What are the chances I will get the new treatment?
5. What are the possible risks, **side effects**, and benefits of the study treatment compared with my current treatment? What other options are available?
6. How could being in this study affect my daily life?
7. How long will the clinical trial last?
8. Will there be any travel or other costs to consider while I am in the trial? If so, can you cover any of these expenses?
9. Where will the study take place? Will I have to stay in the hospital?
10. Will you provide a way for me to get to the study site if I need it?
11. Will you tell me the results of the study? How will I be told?
12. Where can I find out about other studies if I am not a good fit for this one?

Why is it important for everyone to be included in clinical trials?

It is important for clinical trials to have people of different ages, sexes, races, cultures, and health conditions. A drug, device, or other treatment may work differently in one group than in another. Having different groups of people take part helps doctors know if the treatment works for everyone.

Many older people have special health needs that are different from those of younger people. For example, as people age, their bodies may react differently to drugs. Older adults may need different doses of a drug to work well. Also, some drugs may have different side effects in older people than younger people.

Researchers know that it can be hard for some older people to join a clinical trial. Talk to the researchers if you have any of these concerns:

- If you have many health problems, can you join a trial that is looking at only one problem?
- If you are frail or disabled, will you be strong enough to take part?
- If you no longer drive, how can you get to the study site?

The research team may have a plan to make it easier for you to take part in the trial.

Mark's story

Mark is 67 years old and has heart disease. He is not sure about clinical trials. He does not want to feel like a lab rat or take the chance of getting a placebo or a treatment that may not work or makes him feel worse. His doctor talked with Mark about clinical trials—what they are, how they work, and why they need volunteers. She explained that there are both risks and benefits of clinical trials and described how people who volunteer for trials are protected. This information helped Mark feel better about clinical trials. He plans to learn more about how to join a trial.

What are the benefits and risks of a clinical trial?

You may wonder, "Why should I try something researchers are not sure will work?" That is a good question. Being part of a clinical trial may have risks, but it may also have benefits.

Benefits of a clinical trial

- You may get a new treatment for a disease before it is available to everyone.
- You may help others get a better treatment for their health problems in the future.
- You play a more active role in your own health care.
- You can help researchers find new ways to prevent, detect, and treat diseases.

Risks of a clinical trial

- The new treatment may cause side effects or may be uncomfortable.
- The new treatment may not work, or it may not be better than normal care.
- For randomized studies, you may NOT be part of the **treatment group** that gets the new treatment. Instead, you may be part of the **control group**, which means you get the normal treatment or no treatment (a placebo).
- The clinical trial could take time, or you may need to travel to the study site several times.

Lian's story

Lian is 68 years old. She is often very sick and in a lot of pain, but her medicine has stopped working for her. Her sister told her about a study testing a new medicine.

Lian contacted the study. After answering some questions, she found out that she was a good match for the study. But, she was concerned about her safety and privacy and the treatment she would get. A person from the study sat with her to explain everything in detail and answer all of her questions. Lian was so relieved. After that, she signed a form to show that she understood everything and agreed to take part in the study.

How your safety and privacy will be protected

The history of medical research is not perfect. Based on years of experience and learning, Congress has passed laws to protect people who take part in clinical trials. Today, every **investigator** must follow strict rules to make sure that every person in a clinical trial is safe. These rules are enforced by the Federal Government. Also, each clinical trial follows a careful study plan (called a **protocol**) that describes exactly what the researchers will do.

All clinical trials in the United States must be approved by an Institutional Review Board, or IRB. The IRB is made up of doctors, scientists, and people like you who make sure that risks to people are as low as possible.

The informed consent process also helps protect people who volunteer for trials by making sure they understand everything about the trial they are joining.

Federal rules protect the safety of participants in clinical trials.

If you are considering joining a trial, you have the right to:

- Learn about all the treatment options for your health condition.
- Learn all that is involved in the trial, including details about treatment, tests, and possible risks and benefits.
- Discuss the trial with the study doctor and study team.
- Hear and read the information in language you can understand.
- After discussing the study with you, the research team will give you an informed consent form to read. The form includes written details about the information that was discussed with you and describes the privacy of your medical records. If you agree to take part in the trial, you sign the form.
- Even after you sign the consent form, you can leave the trial at any time. You can always ask questions. And the study team will tell you about new information as it becomes available.

For more information

The following groups can help you learn more about clinical trials and search for clinical trials that may be right for you.

General information

National Institutes of Health (NIH)

NIH Clinical Research Trials and You
www.nih.gov/health-information/nih-clinical-research-trials-you

ClinicalTrials.gov
www.clinicaltrials.gov
(searchable online database of trials and studies)

U.S. Food and Drug Administration (FDA)

1-888-463-6332 (toll-free)
druginfo@fda.hhs.gov
www.fda.gov
www.fda.gov/ForPatients/ClinicalTrials/default.htm

Matching services and registries

www.nia.nih.gov/health/registries-and-matching-services

Alzheimer's and related dementias research

Alzheimer's and related Dementias Education and Referral (ADEAR) Center
1-800-438-4380 (toll-free)
adear@nia.nih.gov
www.alzheimers.gov

Find Alzheimer's disease and related dementias clinical trials:
www.nia.nih.gov/alzheimers/clinical-trials

Find Alzheimer's disease research centers:
www.nia.nih.gov/health/alzheimers-disease-research-centers

To learn more about health and aging:

National Institute on Aging Information Center

1-800-222-2225 (toll-free)
1-800-222-4225 (TTY/toll-free)
niaic@nia.nih.gov
www.nia.nih.gov

Visit www.nia.nih.gov/health to find more health and aging information from NIA and subscribe to email alerts. Visit https://order.nia.nih.gov to order free print publications.

Share this booklet with friends and family so they can learn about clinical research and participating in clinical trials.

Words to know

Control group

(pronounced kun-TROLE groop)
The group of people who get the placebo or normal treatment or no treatment at all. Not all clinical trials have a control group.

Informed consent

(pronounced in-FORMD kun-SENT)
Before a person agrees to take part in a clinical trial, researchers explain the details—what the study is trying to find out, how long it will last, what will happen, and possible benefits and risks. You sign a form showing that you understand what will happen during the study and want to be part of it.

Investigator

(pronounced in-VES-tih-gay-ter)
A researcher who works on a clinical trial. The lead researcher for a study is called the principal investigator.

Placebo

(pronounced pluh-SEE-boh)
A pill or other treatment that looks like the treatment or drug being tested but has no medicine in it. A placebo is sometimes called a "sugar pill." Researchers often compare what happens to people using the study treatment with what happens to those taking the placebo.

Protocol

(pronounced PROH-tuh-KOL)
A detailed study plan that answers specific research questions and protects people. The protocol describes the type of people who can take part in the study, the tests they will receive, how long the study will last, and how researchers will determine the benefits and risks.

Randomization

(pronounced RAN-duh-mih-ZAY-shun)
The process of assigning people to different groups in a clinical trial. Participants are assigned by chance (like the flip of a coin). A computer is usually used to assign people to a group. Neither participants nor doctors can pick which group a person is assigned to.

Side effects

(pronounced side eh-FEKTZ)
Bad effects caused by a treatment. Examples of common side effects are headache, nausea, and skin irritation. Sometimes side effects can be more serious, even life-threatening.

Study coordinator

(pronounced STUH-dee koh-AWR-din-ey-ter)
The person you can contact with questions about the study or your participation. Sometimes called the clinical research coordinator.

Treatment group

(pronounced TREET-ment groop)
The group of people who get the treatment being tested in the clinical trial. Results from the treatment group are compared with those from the control group to see if the new treatment is better and/or safer.

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