
Participating
in Alzheimer's Research
For yourself and future generations
NIH
National Institute
on Aging

When I was diagnosed with Alzheimer's disease, I wanted to do everything possible to fight the disease, not give in to it. I talked with my doctor about possible treatments. He helped me find a clinical trial that was right for me. Now I get to talk with Alzheimer's experts. Plus, I know I'm doing something that might help my children and grandchildren avoid the disease.

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Introduction

This is an exciting time for Alzheimer's disease clinical research. Thanks to advances in our understanding of this brain disorder and powerful new tools for "seeing" and diagnosing it in people, scientists are making great strides in identifying potential new ways to help diagnose, treat, and even prevent Alzheimer's. These advances are possible because thousands of people have participated in Alzheimer's clinical trials and other studies to learn more about the disease and test treatments. We know what we know because of them.

You may have heard of clinical trials and research studies but are not sure what they are or if you want to join one. This booklet provides information

Today, at least 70,000 volunteers are urgently needed to participate in more than 150 active clinical trials and studies in the United States that are testing ways to understand, treat, prevent, or cure Alzheimer's disease. All kinds of people, including healthy volunteers, are needed.

to help you decide if participating in a clinical trial or study is right for you, a friend, or family member.

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

You can make a difference by participating in research.

Types of Clinical Research

Clinical research is medical research involving people. There are two types, clinical studies and clinical trials.

Clinical Studies

Clinical (sometimes called observational) studies observe people in normal settings. Researchers gather information, group volunteers according to broad characteristics, and compare changes over time. Alzheimer's disease studies may help identify new possibilities for clinical trials.

For example, the Alzheimer's Disease Neuroimaging Initiative studies brain images and biomarkers (biological signs of disease) in people with normal cognitive aging, mild cognitive impairment—a disorder that may precede Alzheimer's disease—and early-stage Alzheimer's to better understand the disease and its progression. The researchers discovered that certain changes in blood or cerebrospinal fluid may signal early Alzheimer's in people with normal cognition. Now, that knowledge is being used to test treatments for Alzheimer's *before* symptoms, like changes in memory, begin.

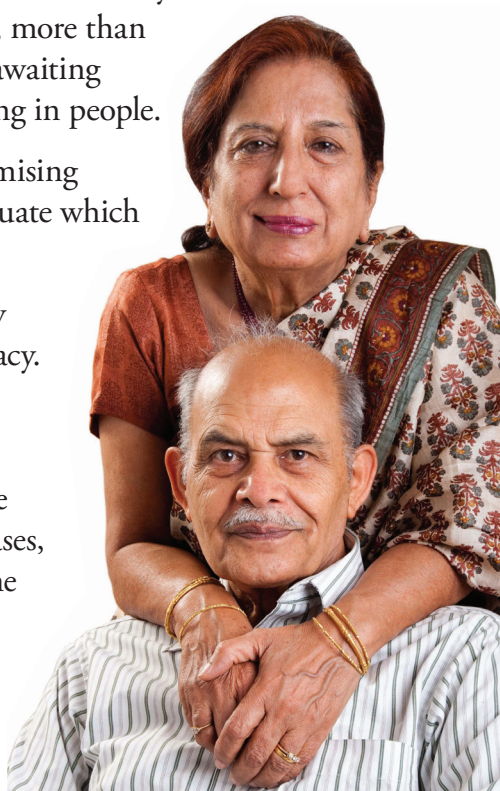
Clinical Trials

Clinical trials test interventions, such as drugs or devices, as well as diet or lifestyle changes. Drug testing is the focus of many clinical trials. Currently, more than 70 drugs are in clinical trials for Alzheimer's disease, and more are awaiting U.S. Food and Drug Administration (FDA) approval to begin testing in people.

Clinical trials are the primary way that researchers find out if a promising treatment is safe and effective in people. Clinical trials also can evaluate which treatments are more effective than others.

Before FDA-approved clinical trials begin, scientists perform laboratory tests and studies in animals to test a potential therapy's safety and efficacy. If these studies show favorable results, the FDA gives approval for the intervention to be tested in humans.

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects. If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the FDA approves it for clinical use and continues to monitor its effects.



Common Questions About Participating in Research

How can I find out about Alzheimer's trials and studies?

Check the resources below or contact the organizations on pages 18–20:

- Ask your doctor, who may know about local research studies that may be right for you.
- Sign up for a registry or a matching service (see page 19) to be invited to participate in studies or trials when they are available in your area.
- Contact Alzheimer's disease centers or memory or neurology clinics in your community. They may be conducting trials.
- Visit the Alzheimer's Disease Education and Referral (ADEAR) Center clinical trials finder, *www.nia.nih.gov/alzheimers/clinical-trials*.
- Look for announcements in newspapers and other media.
- Search *www.clinicaltrials.gov*.

Why Would I Participate in a Clinical Trial?

There are many reasons why you might choose to join an Alzheimer's clinical trial. You may want to:

- Help others, including future family members, who may be at risk for Alzheimer's disease
- Receive regular monitoring by medical professionals
- Learn about Alzheimer's and your health
- Test new treatments that might work better than those currently available
- Get information about support groups and resources

What else should I consider?

While there are benefits to participating in a clinical trial or study, there are some risks and other issues to consider as well.

Risk. Researchers make every effort to ensure participants' safety (see pages 12–13). But, all clinical trials have some risk. Before joining a clinical trial, the research team will explain what you can expect, including possible side effects or other risks. That way, you can make an informed decision about joining the trial.

Expectations and motivations. Single clinical trials and studies generally do not have miraculous results, and participants may not benefit directly. With a complex disease like Alzheimer's, it is unlikely that one drug will cure or prevent the disease.

Uncertainty. Some people are concerned that they are not permitted to know whether they are getting the experimental treatment or a placebo (inactive treatment), or may not know the results right away. Open communication with study staff can help you understand why the study is set up this way and what you can expect.

Time commitment and location. Clinical trials and studies last days to years. They usually require multiple visits to study sites, such as private research

facilities, teaching hospitals, Alzheimer's research centers, or doctors' offices. Some studies pay participants a fee and/or reimburse travel expenses.

Study partner requirement. Many Alzheimer's trials require a caregiver or family member who has regular contact with the person to accompany the participant to study appointments. This study partner can give insight into changes in the person over time.

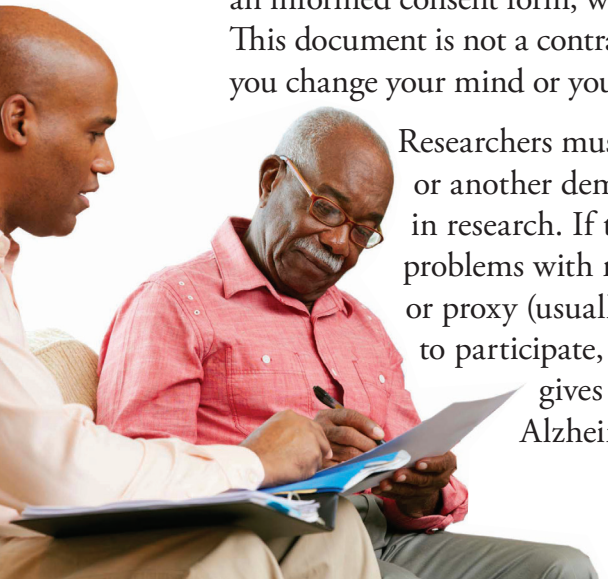
What happens when a person joins a clinical trial or study?

Once you identify a trial or study you are interested in, contact the study site or coordinator. You can usually find this contact information in the description of the study, or you can contact the ADEAR Center (see page 18). Study staff will ask a few questions on the phone to determine if you meet basic qualifications for the study. If so, they will invite you to come to the study site. If you do not meet the criteria for the study, don't give up! You may qualify for a future study.

What is informed consent?

It is important to learn as much as possible about a study or trial to help you decide if you would like to participate. Staff members at the research center can explain the study in detail, describe possible risks and benefits, and clarify your rights as a participant. You and your family should ask questions and gather information until you understand it fully.

After the research is explained and you decide to participate, you will be asked to sign an informed consent form, which states that you understand and agree to participate. This document is not a contract. You are free to withdraw from the study at any time if you change your mind or your health status changes.



Researchers must consider whether the person with Alzheimer's disease or another dementia is able to understand and consent to participate in research. If the person cannot provide informed consent because of problems with memory and thinking, an authorized legal representative, or proxy (usually a family member), may give permission for the person to participate, particularly if the person's durable power of attorney gives the proxy that authority. If possible, the person with Alzheimer's should also agree to participate.

Steps in Clinical Trial Participation

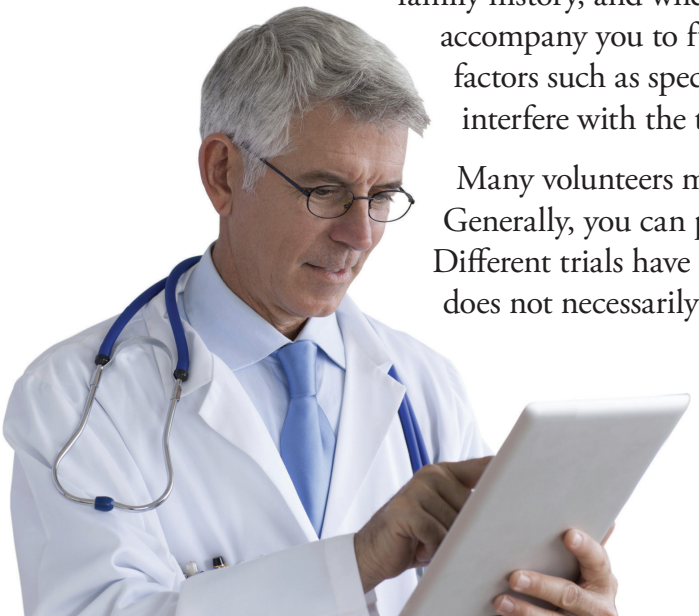
Here's what happens in a trial.

1. Study staff explain the trial in detail and gather more information about you.
2. Once you have had all your questions answered and agree to participate, you sign an informed consent form.
3. You are screened to make sure you qualify for the trial (see page 12).
4. If accepted into the trial, you schedule a first visit (called the "baseline" visit). The researchers conduct cognitive and/or physical tests during this visit.
5. You are randomly assigned to a treatment or control group.
6. You and your family members 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. At these visits, the research team collects information about effects of the intervention and your safety and well-being.
8. You continue to see your regular physician for usual health care throughout the study.

How do researchers decide who will participate?

After you consent, you will be screened by clinical staff to see if you meet the criteria to participate in the trial or if anything would exclude you. The screening may involve cognitive and physical tests.

Inclusion criteria for a trial might include age, stage of dementia, gender, genetic profile, family history, and whether or not you have a study partner who can accompany you to future visits. Exclusion criteria might include factors such as specific health conditions or medications that could interfere with the treatment being tested.



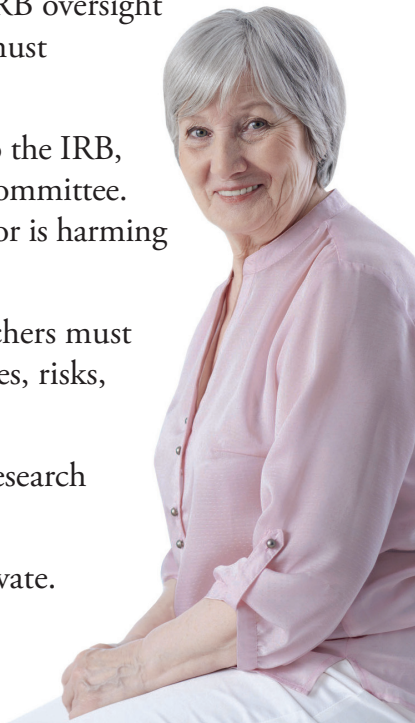
Many volunteers must be screened to find enough people for a study. Generally, you can participate in only one trial or study at a time. Different trials have different criteria, so being excluded from one trial does not necessarily mean exclusion from another.

How will my safety be protected?

Congress has passed laws to protect study participants. Today, researchers are required to

follow strict rules to make sure that every participant is safe and information remains confidential. These rules are enforced by the Federal Government. Here are some of the safeguards in place:

- **Institutional Review Board (IRB).** Every study site must have IRB oversight to ensure participants are not exposed to unnecessary risk. The IRB must include at least one public member.
- **Data and Safety Monitoring (DSM) committee.** In addition to the IRB, clinical trials with potential safety concerns are monitored by a DSM committee. If the committee finds that the experimental treatment is not working or is harming participants, it will stop the trial right away.
- **Informed consent.** Before a volunteer agrees to participate, researchers must explain the details of the study: purpose, duration, required procedures, risks, and potential benefits.
- **Right to withdraw.** Even if volunteers sign up to participate in a research study, they can decide to withdraw at any time during the study.
- **Privacy.** Researchers must keep health and personal information private.



Why Placebos Are Important

In undertaking a clinical trial, researchers don't want to leave anything to chance. They want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The "gold standard" for testing interventions in people is the "randomized, placebo-controlled" clinical trial. That means volunteers are randomly assigned—that is, selected by chance—to either a test group receiving the experimental intervention or a control group receiving a placebo or standard care. A placebo is an inactive substance that looks like the drug or treatment being tested.

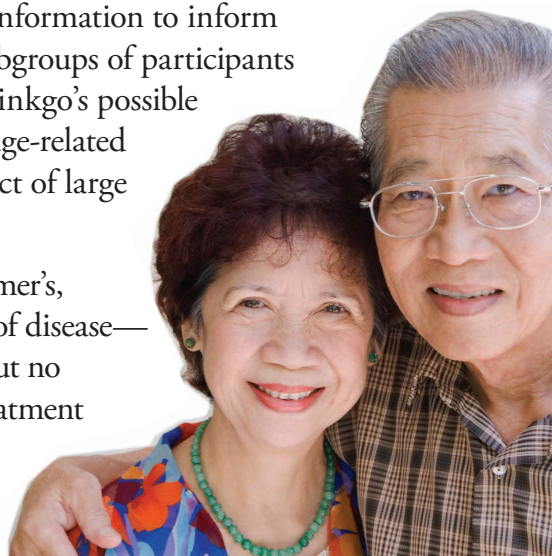
Comparing results from the two groups suggests whether changes in the test group result from the treatment or occur by chance. In many trials, no one—not even the research team—knows who gets the treatment, the placebo, or another intervention. When participants, family members, and staff all are "blind" to the treatment while the study is underway, the study is called a "double-blind, placebo-controlled" clinical trial.

Learning from Research Findings

Test and placebo groups are equally important, as shown by the results of numerous clinical trials. For example, early research suggested that ginkgo biloba, an herbal supplement, might be effective in delaying dementia. To find out, the National Institutes of Health (NIH) sponsored a 6-year, Phase 3 clinical trial with more than 3,000 participants age 75 and older. At the end of the trial, scientists reported that they had found no significant differences in effect on dementia in adults who received ginkgo biloba or the placebo.

This result was disappointing, but scientists gained a wealth of information to inform future research. For example, researchers learned more about subgroups of participants who may be at greater risk for developing dementia and about ginkgo's possible effects on cardiovascular disease, cancer, depression, and other age-related conditions. They also gained insights into the design and conduct of large dementia prevention trials in older adults.

Based on the results of this and other trials in people with Alzheimer's, scientists have begun to test treatments in people at earlier stages of disease—that is, people who may have Alzheimer's-related brain changes but no memory loss or other symptoms. Many researchers think that treatment earlier in the disease process may help prevent or delay dementia.



Questions to Ask About Clinical Trials and Studies

Here are some questions to ask the research team when you are thinking about a trial or study.

- What is the purpose?
- What tests and treatments will be given?
- What are the risks? What side effects might occur?
- How long will the study last? How much time will it take at each visit?
- Where and when will the testing occur? How frequent are the visits?
- Can I continue treatments for Alzheimer's and other conditions as prescribed by my regular doctor?
- How will you keep my doctor informed about my participation in the trial?
- Does the study compare standard and experimental treatments?
- How will the trial affect my everyday activities?
- If I withdraw, will this affect my normal care?
- Will I learn the results of my tests? Of the study overall?
- What are the chances that I will receive a placebo?
- What steps ensure my privacy?
- Will my expenses be reimbursed?
- Will I be paid?

Clinical Trials and Studies Need All Kinds of People

Clinical trials and studies are a partnership between researchers and volunteer participants, who work together to answer questions we can answer in no other way. To ensure that answers are correct, we need volunteers of all kinds: men and women, African Americans, Latinos, Native Americans, Asian Americans, whites, people with Alzheimer's or a family history of the disease, people with conditions that may lead to Alzheimer's, and healthy volunteers.

An intervention may work differently in one group than in another. Without adequate representation of a particular group, questions about a treatment in that group may remain unanswered.

In addition to diversity, the number of people included in research can affect results. Without enough participants, trials may be delayed or produce limited or inconclusive results.

For More Information

To find out more about participating in clinical trials and studies, talk with your health care provider or contact any of the organizations listed below.

Alzheimer's Disease Education and Referral (ADEAR) Center

1-800-438-4380 (toll-free)
adear@nia.nih.gov
www.nia.nih.gov/alzheimers

Find Alzheimer's and cognitive impairment trials: *www.nia.nih.gov/alzheimers/clinical-trials*

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

Visit NIH's ADEAR website to learn more about Alzheimer's and other dementias, find clinical trials, and sign up for email updates to hear about new trials. The ADEAR Center offers information and publications for families, caregivers, and professionals on diagnosis, treatment, patient care, caregiver needs, long-term care, education and training, and research related to Alzheimer's disease.

Matching Services and Registries

Alzheimer's Association
1-800-272-3900 (toll-free)
www.alz.org

The Alzheimer's Association has a clinical trial service, TrialMatch®, at *www.alz.org/trialmatch*. The Association is a national, nonprofit organization with a network of local chapters that provide education and support for people diagnosed with Alzheimer's disease, their families, and caregivers.

ResearchMatch
www.ResearchMatch.org/roar

ResearchMatch is an NIH-funded service that helps match people interested in clinical trials with researchers. Anyone with an email address can join, and members are invited to participate in many kinds of studies and trials.

Alzheimer's Prevention Registry
www.endALZnow.org

The Alzheimer's Prevention Registry is an online community open to anyone age 18 or older who wants to learn about and possibly participate in Alzheimer's prevention studies.

Alzheimer's Disease Cooperative Study (ADCS)

www.adcs.org

The ADCS, funded by NIH's National Institute on Aging, is a consortium of medical research centers and clinics working to develop and test drugs to treat Alzheimer's disease.

General Information About Research Participation

National Institutes of Health (NIH)

- NIH Clinical Research Trials and You: *www.nih.gov/health/clinicaltrials*
- ClinicalTrials.gov: *www.clinicaltrials.gov* (searchable online database of trials and studies)

U.S. Food and Drug Administration (FDA)

- Participating in Clinical Trials: *http://patientnetwork.fda.gov/find-out-about-clinical-trials*

The FDA regulates all U.S. clinical trials of drugs and devices and offers information and resources for clinical trial participants and professionals.

NIH Publication No. 14-7484

August 2014