

Overview

Clinical trials are research studies conducted with human volunteers to determine whether treatments are safe and effective. Without clinical research and the help of participants, there can be no treatments, prevention or cure for Alzheimer's disease.

Participating in clinical studies is one way I can fight back, and work to provide a dementia-free world for my children and grandchildren.



Karen W.

Living with Alzheimer's disease
TrialMatch user

The [Alzheimer's Association TrialMatch®](#) database includes:

- [Treatment trials](#) to test new drug and non-drug based dementia treatments or combinations of treatments.
- [Diagnostic studies](#) that find new tests or procedures for diagnosing a disease or condition.
- [Prevention trials](#) that investigate ways to prevent the onset of diseases.
- [Quality of life studies](#) that explore ways to improve quality of life for individuals who have a chronic illness, their caregivers and family members.
- [Online studies](#), which are web-based research conducted entirely online.

Treatment trials

Don't just hope for a cure — help us find one.

TrialMatch is a free clinical trials matching service that connects individuals with Alzheimer's, caregivers and healthy volunteers to current research studies.

[Start TrialMatch](#)

Perhaps the best known clinical studies are those that test new treatments. Before a new drug or treatment can be approved by the Food and Drug Administration (FDA), it has to go through three phases of clinical trials. Most of the time, a clinical trial is designed to compare a new therapy with the best-known existing therapy for the disease being studied. When there is no proven treatment to use as a comparison, researchers are likely to compare the new drug with a placebo, which is a sugar pill or other inactive substance that has no treatment value but made to look like the new drug in development.

There are two types of Alzheimer's treatment trials:

- Treatments aimed at reducing symptoms. During this type of trial, new drugs and variations of existing drugs that aim to reduce the symptoms of Alzheimer's disease are tested. Studies of existing drugs explore whether changing the dose, taking the medication on a different schedule (more

or less often), or combining it with other medications might further reduce or delay symptoms.

- Treatments aimed at slowing or stopping the disease.
During this type of trial, new drugs designed to slow or stop Alzheimer's are tested. Some of the experimental drugs being tested in treatment trials represent entirely new ways of treating the disease.

What's the difference between a clinical trial and a clinical study?

Clinical trials are sometimes referred to as clinical studies; the terms are often used interchangeably, but there are subtle differences between them. Clinical trials test new interventions or drugs to prevent, detect or treat disease. A clinical study is any type of clinical research involving people, regardless of whether it is testing a specific intervention.

Diagnostic studies

Many clinical studies focus on finding better ways to accurately diagnose Alzheimer's disease, particularly in the early stages. These studies will hopefully lead to a trusted and easy-to-apply method that enables physicians to diagnose persons at risk for the disease — even before symptoms appear — and begin

treatment (once such Alzheimer's treatments exist) in time to prevent the development of dementia.

Diagnostic studies are vital to the advancement of Alzheimer's research because they identify which individuals to treat and provide doctors with a way to track whether a treatment is working.

Other types of research

Researchers are working to uncover as many aspects of Alzheimer's disease and other dementias as possible.

Examples include:

- Prevention trials, where researchers look for ways to stop Alzheimer's disease from developing, oftentimes in groups of people identified as being at higher risk. These studies look at whether a certain medication, vitamin or lifestyle change (for example, healthy eating or exercise) might prevent Alzheimer's.
- Quality of life studies, where researchers try to better understand and address the needs of people with Alzheimer's, their caregivers and family members. These studies' goal is to figure out what types of support, education or training solve some of the challenges that those impacted by the disease face.

- Online studies, which often explore the same kinds of questions as other studies but are able to be completed online, without requiring a visit to a particular site.

You can also help advance Alzheimer's research by volunteering for a clinical study. Get started by exploring [TrialMatch](#), a free, easy-to-use clinical studies matching service that allows you to see which studies are a good fit for you or a family member.

What progress has been made?

Since TrialMatch launched in July 2010, more than 370,000 individuals have signed up and gained access to hundreds of clinical studies — providing dementia researchers with volunteers to investigate potential treatments, disease progression and methods of prevention.

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Clinical trials test new interventions or drugs in a series of steps (or phases) to prevent, detect or treat disease. During this sequence of testing, researchers gradually build evidence about whether an intervention or drug is effective and whether it has an acceptable safety profile — that is, whether the risks associated with its use are reasonable given its potential benefit.

Phases of pharmacological (drug) clinical trials

New drugs must successfully complete a three-phase clinical trial process (Phase I, Phase II and Phase III) before being approved for use by the Food and Drug Administration (FDA); they must perform well enough in each phase to progress to the next one. Preclinical studies in laboratories establish a scientific basis for believing a drug is reasonably safe and may be effective.

- Phase I trials, the first stage of human testing, typically involve fewer than 100 volunteers and look at the risks and side effects of a drug. Participants at this phase are often healthy volunteers.
- Phase II trials enroll up to a few hundred volunteers who have the condition the drug is designed to treat. These studies provide further information about safety and help to

determine the best dosage of a drug, and are generally too small to provide clear evidence about a treatment's benefit.

- Phase III trials enroll several hundred to thousands of volunteers, often at multiple study sites worldwide. They provide the chief evidence for safety and effectiveness that the FDA will consider in deciding whether to approve a drug.
- Phase IV trials, also called post-marketing studies, are often required by the FDA after a drug is approved. During this phase, researchers continue to monitor the health of people taking the medication to gain further insight into its long-term safety and effectiveness.

Criteria to participate

Before joining a clinical trial, an individual must qualify for the study. All clinical trials have guidelines about who can participate. Researchers define these guidelines as inclusion and exclusion criteria. Examples of these criteria include:

- Limiting participants to a certain age range.
- Requiring participants to be in a certain stage of the disease being studied.
- Not allowing health conditions other than the one being studied.
- Not permitting use of certain medications other than the study drug.
- Requiring participation of a caregiver or “study partner.”

Individuals living with dementia, caregivers and healthy volunteers without dementia are needed for Alzheimer's clinical trials. To find a study that matches your personal eligibility, visit [Alzheimer's Association TrialMatch®](#).

Placebos

Scientists have learned that people sometimes feel better, and even have improved results on medical tests, when they believe a treatment is helping them. Doctors may also convince themselves a treatment is working because they care about their patients.

There are two main strategies to reduce the likelihood that hopes and beliefs will affect the outcome of clinical trials:

1. Trials are placebo-controlled. Study participants are randomly chosen to receive the experimental treatment and some receive a placebo, an inactive pill, liquid or powder that has no treatment value. Experimental treatments are often compared to placebos to assess effectiveness.
2. Trials are “double-blinded.” Participants and study staff are unaware of who receives the drug and who gets the placebo.

When a standard of care — a typical treatment plan for a condition — is available, it is often used instead of a placebo. In such cases, the experimental treatment and the standard

treatment are compared.

Safety

Although participants and study staff don't know who's getting the treatment and who's getting the placebo, most trials have a separate, independent Data Safety and Monitoring Committee that has access to this information. Committee members regularly analyze data and step in if they notice any worrisome patterns of serious side effects.

Informed consent

Informed consent is the process of learning key facts about a study before deciding whether to volunteer. The FDA requires potential participants to have complete information about the study in writing. Study staff members are required to meet with each prospective participant to explain risks, possible benefits and answer any questions. People who decide to join the study must sign an informed consent form. Individuals who are invited to participate in a study are not required to join. Participants are free to leave a study at any time.

Capacity and proxy issues

Some cognitively impaired individuals are still able to make informed decisions for themselves about participating in research. His or her attending physician can provide a medical

opinion about an individual's decision making capacity. While an individual still has decision-making capacity, he or she may choose to execute a [health care power of attorney](#) or other [power of attorney](#) under his or her's resident state laws that appoints an individual or entity as his or her agent to make health care decisions for that person. If an individual is determined to no longer have decision making capacity and does not have a health care power of attorney or other power of attorney in place, a court will have to appoint a legal guardian to make health care decisions for that person.

Sometimes individuals in the early stages of a disease establish an advance directive that specifies whether or not they wish to be considered for clinical research should they no longer be able to decide for themselves. Learn more about advance directives from your personal attorney.

An organization or institution's Institutional Review Board (IRB) determines safety and the level of risk associated with a clinical trial. When a clinical trial is believed to be of minimal risk, an individual's representative or guardian may give consent for that person to participate, as long as that individual does not have an advance directive in place that says he or she does not want to be enrolled in a research study or clinical trial.

If an organization or institution's IRB determines that the clinical trial poses a greater than minimal risk but is reasonably likely to provide a benefit to an individual living with Alzheimer's or dementia, a representative or guardian may enroll the individual

in the trial if the representative or guardian believes the trial is in the individual's best interests. Or, a previously executed research-specific advance directive may also be used to enroll the participant in the trial.

If an IRB determines that a clinical trial poses greater than minimal risk without a reasonable potential benefit to the individual, only those individuals who (1) are capable of giving their own informed consent or (2) have previously executed a research-specific advance directive stating that they would like to be enrolled in clinical research, are allowed to participate. If the individual has executed a research-specific advance directive, that person's representative or guardian must be available to monitor the individual's participation in the clinical trial.

When clinical trials end

All clinical trials end, and while the early termination of a trial may cause strong emotions in participants, it's important to understand that researchers have gathered important data even if the results aren't positive. Everything we know about current and potential Alzheimer's treatments has come from clinical trials, including those that didn't meet their intended outcomes.

All trial participants are notified of important changes to their study. This process can be complicated when a trial ends early.

Learn more: [When Clinical Trials End](#)

Myth: There are already plenty of volunteers. They don't need me to participate.

Fact: New treatments for Alzheimer's disease are nearly impossible without clinical trials, and many more participants — including people with dementia or those who are at risk of developing it, caregivers and healthy volunteers with no dementia issues — are urgently needed. Hundreds of [clinical studies are now recruiting participants](#).

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Myth: It's too late — the disease is too advanced to participate in a research study.

Fact: There are clinical studies that work with people in every stage of Alzheimer's. Participating in a trial could have a potentially measurable impact on the disease.

Myth: Clinical trials are dangerous because they use new and unproven methods and medications.

Fact: Clinical trials are experiments and, as a result, always involve some level of risk. However, the ethical and legal codes

that govern medical practice also apply to clinical trials. In addition, most large clinical trials are federally regulated with built-in safeguards to protect participants. However, there may be unpleasant, serious or even life-threatening side effects to experimental treatment. Participants should discuss and understand any side effects with their doctor, and if necessary, may withdraw at any time.

Myth: If I join a clinical trial, I won't receive the same quality of care that I currently have with my doctor.

Fact: Participants in clinical trials receive a high standard of care. All participants have the opportunity to talk with study staff, and should also continue care with their doctors.

For people living with the disease, research shows that those involved in clinical studies do somewhat better than people in a similar stage of their disease who are not enrolled, regardless of whether the experimental treatment works. This may result from the general high quality of care provided during clinical studies.

Myth: If I join a treatment clinical trial, I will get a placebo.

Fact: In a randomized clinical trial, it is often the case that some of the participants get a placebo as part of the trial design. Each potential participant should consider his or her comfort level in not knowing whether they will receive the experimental treatment or a placebo before deciding to join a trial.

Myth: There may be painful or invasive procedures as part of the clinical trial.

Fact: Each potential clinical trial participant should inquire about

the trial design and the potential treatments and procedures they may receive during the study before deciding whether to join a trial. Volunteers can withdraw from a study at any time they or their physician feels it is in their best interest.

In addition, there are many studies that do not use experimental medications. You can find a clinical study that is right for you at [Alzheimer's Association TrialMatch®](#).

Myth: It costs too much to participate in a clinical trial.

Fact: Every clinical trial is different. Some clinical trials reimburse associated travel costs, and some may provide compensation to participants. Still, there may be costs associated with participating, so contact your trial site for information pertaining to a particular trial of interest.

Myth: I am going to be rejected from a clinical trial because I have another disease or condition.

Fact: Some people living with Alzheimer's disease also have other chronic medical conditions, such as heart disease, diabetes or cancer. However, they may still qualify for a clinical trial. Each clinical study has different inclusion and exclusion criteria. Check with the trial site or [TrialMatch](#) for more details.

Myth: If there is a clinical trial that could help me, my doctor will tell me about it.

Fact: With hundreds of clinical studies being conducted across the country and online, your physician may be unaware of which studies are in your area. For the most up-to-date information about these studies, use [TrialMatch](#).

Myth: If a clinical trial ends early, my participation wasn't meaningful.

Fact: All clinical studies — even unsuccessful ones — help scientists learn. Everything we know about current and potential Alzheimer's treatments has come from clinical trials, including those that didn't meet their intended outcomes.