

CURING ALZHEIMER'S

CLINICAL TRIALS *are the* KEY

UsAgainstAlzheimer's

Curing Alzheimer's

CLINICAL TRIALS ARE THE KEY

If you've been affected by Alzheimer's disease or mild cognitive impairment, there's something you – and *only* people like you – can do to help find a cure for Alzheimer's: participate in a clinical trial. *Your* body may hold the answers to medical researchers' questions about the disease. If you're in a clinical trial, you're part of the research team working to find ways to prevent or treat Alzheimer's.

Clinical trials look at new ways to detect, prevent, or cure disease. Often, people who participate in clinical trials learn more about their own condition from medical experts using advanced technology. Sometimes, participants are the first people to benefit from a new treatment. Trials are designed to be safe, and as convenient as possible.

One of the keys to curing Alzheimer's is getting enough people in the early stages of the disease into clinical trials. That's how we're going to find out which treatments are most effective at slowing, stopping, or preventing the disease.

Alzheimer's researchers need more people to participate in clinical trials. Alzheimer's researchers spend a lot of time and money on recruitment. It would be better if they could spend that time and money on science to find a cure. The sooner you connect with a clinical trial, the better.

You can find Alzheimer's or dementia clinical trial or study sites near you by visiting UsAgainstAlzheimers.org/research and entering your ZIP code. Then call the site nearest you and tell the person who answers that you are interested in learning about being in a

clinical trial or study. If you don't have access to a computer, you can call the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380 and ask for the phone number of a clinical trial or study site near you.

If you participate in a clinical trial, you'll personally benefit from the knowledge of the medical team running it. They'll use state-of-the-art tests and scans to monitor your brain. They know Alzheimer's disease and brain health, so they understand what you're experiencing and can help answer your questions.

For some people, the experimental treatment in a clinical trial could improve their health. Think about it: the first person to be cured of Alzheimer's will be someone in a clinical trial.

By participating in a clinical trial, you're increasing the odds that if your kids or grandkids or other friends or family get the disease in the future, there will be a cure. Participating in an Alzheimer's research clinical trial is one way you can make a choice to exert power over the disease, embrace hope for the future, and ultimately, help find treatments and cures.

Things to Know About Clinical Trials

Clinical trials are the key to accelerating a cure to Alzheimer's disease. Any treatment for Alzheimer's is going to be tested in a clinical trial before it is available to the public. But many clinical trials finish late because of difficulties recruiting participants, thereby delaying the discovery of a treatment or a cure.

We need more people with Alzheimer's to participate in clinical trials. Too many trials are proceeding slowly because there aren't enough participants. Your participation makes a difference.

Researchers also need people who don't have Alzheimer's. Alzheimer's starts to form in the brain up to 20 years before symptoms appear, so researchers need to study healthy people to see how their brains change over time. They especially want to study people who have a family history of dementia, past brain injuries or results from genetic tests that show increased risk.

Trials need more people just like you. Alzheimer's affects men and women of all racial and ethnic backgrounds. African-Americans and Latinos are especially needed in clinical trials, so researchers can learn why they are more likely to get Alzheimer's and find treatments that work for everyone.

Clinical trials are designed with safety in mind. Every clinical trial for Alzheimer's research must be approved by an Institutional Review Board (IRB) before it begins. The IRB is made up of a diverse group of scientists and non-scientists who review the research specifically to protect the rights and welfare of people who are research participants. The IRB can approve or disapprove the research, or require changes before it can begin. The IRB continues to review the research periodically while it is underway.

The researchers running the trial will show you respect. The people running the trial will appreciate your involvement and thank you. Without participants, there are no clinical trials. Many trial participants comment about how respected and appreciated they feel.

You are strong enough to participate. Don't assume you are too old or frail to participate. If you fit the description of potential participants, get in touch with the researchers. They would rather hear from you even if the trial isn't a good match for you than not hear from you at all. All of those conversations and steps can make a difference.

You can find time to participate. Let the clinical trial organizers know your time limitations and they will do what they can to facilitate your involvement by trying to find a trial that matches your available time.

You may be able to get help with transportation. There are research centers all over the country located at hospitals, universities, doctors' offices, and community clinics. For some clinical trials, researchers will travel to you. Some sites provide free transportation from your home to the clinic and back home.

If you are not accepted into the first clinical trial to which you apply, you should keep applying. Don't be discouraged, and don't stop applying. Being screened out is not a rejection of you. Different trials have different needs; it just means you may be a better fit for another trial. There are many opportunities to participate in other trials or studies.

About Clinical Trials

Clinical trials are medical research or drug development tests to evaluate new ways to prevent, treat or detect disease. Before a medication or treatment can be offered to the public, federal law requires clinical trials to demonstrate that it is safe and effective. The U.S. Food and Drug Administration is the federal agency that oversees clinical trials for medications.

WHY PARTICIPATE IN A CLINICAL TRIAL?

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To learn about your personal health condition
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To possibly improve your health
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To help future generations
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To FIND A CURE!
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FINDING THE RIGHT CLINICAL TRIAL FOR YOU

How do I find the best clinical trial for me?

Visit UsAgainstAlzheimers.org/research and enter your ZIP code. It will tell you the clinical trial sites near you. Call the site nearest you and tell the person who answers that you are interested in learning about being in a clinical trial or study. If you don't have access to a computer, you can call the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380.

The trial organizers want to hear from you. They will give you more information, even if you are not sure you want to participate. They may set up an appointment for you to learn more or enroll in a trial or study.

There also are online matching services you can use. If you provide your information on a web site for a matching service, it will show you information about clinical trials that may be best for you. You can decide which ones you want to contact about participating.

Another way to connect with a clinical trial is to provide your information to a registry of Alzheimer's clinical trials. If you provide your information to a registry, clinical trial researchers looking for people like you will get in touch with you to let you know about trials that may be a good fit, based on the information you gave the registry.

I don't have problems with my memory or thinking, but I might be at risk. Should I look into clinical trials or studies?

Yes. Researchers believe that detecting Alzheimer's earlier is essential to effectively preventing and treating it. Alzheimer's

starts to form in the brain up to 20 years before symptoms appear. Researchers need people to enroll in clinical studies before they have problems with their memory or thinking. Many of those people won't ever develop dementia, but their participation helps researchers understand what causes it. Researchers especially want people to enroll in clinical trials if their family history, past brain injuries, or the results of genetic tests indicate they have higher risk of developing Alzheimer's.

What is the difference between a clinical trial and an observational study?

Clinical trials are a type of clinical study. In a clinical trial, participants receive specific interventions – like medicines or changes to participants' behavior, such as diet – according to the research plan. Clinical trials may compare a new medical approach to one that is already available, to a placebo that contains no active ingredients, or to no intervention.

An observational study is a different type of clinical study. Participants in an observational study are not assigned specific interventions by the research team. For example, researchers may observe a group of older adults to learn more about the effects of different lifestyles on brain health.

This toolkit talks a lot about clinical trials, and clinical trials need more participants. It's also helpful for people to participate in observational studies and basic research studies. You also can learn about ways to participate in those types of studies by contacting a clinical trial site near you by visiting UsAgainstAlzheimers.org/research or calling the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380.

What to Expect When You Participate in a Clinical Trial



TALKING TO A REPRESENTATIVE OF THE RESEARCH TEAM

Before you enroll in a clinical trial, a representative of the research team will determine if you meet the eligibility criteria to even take the first steps in the trials. They may look at your age, health history, or other factors.

Then they will give you some important information.

- ▷ They will give you a general description of the research and the role of participants.
- ▷ They will tell you that you can stop participating in the trial any time you wish. If you get other care at the same facility, your care will not be diminished if you leave the clinical trial.

- ▷ They will discuss the medication you will receive, including how it works, how it will be administered to you, and how often.
- ▷ They will discuss whether you may be given a placebo, and how likely that is. You benefit from diagnostic tests and expert evaluation even if you get a placebo – and you're helping researchers learn about the disease and get closer to a cure.
- ▷ They will tell you about possible side effects, and how likely they are.
- ▷ They will discuss whether there are any risks from the diagnostic procedures (like different types of brain scans) or the treatment itself.



1. CONTACT A CLINICAL RESEARCH CENTER.

One way: visit [UsAgainstAlzheimers.org/research](https://www.usagainstalzheimer.org/research) and enter your ZIP code – then call.



2. PRESCREENING INTERVIEW.

Do you meet the criteria for age, sex, race and health history?



3. SCREENING.

Diagnostic tests to determine who will continue with the trial.



4. STUDY PERIOD.

You receive the treatment or a placebo, and researchers monitor the effect.



5. FOLLOW UP.

Some studies monitor your health – less frequently – after the study period is over.

What to Expect When You Participate in a Clinical Trial

- ▷ They also should discuss the potential benefits of participation, including the diagnostic value of testing, and the potential health benefits of the treatment.
- ▷ They will tell you what participation in the study will require of you, from your initial consultation to your end-of-study visit, and everything in between, including:
 - How long you're expected to participate
 - Where you'll visit, how many times, and how frequently
 - Whether there's an extension study. If the trial shows promise, you may be able to get treatment for an extended period if you participate in the extension study
 - Whether you'll receive a fixed stipend to cover expenses or another payment, and how much.
- ▷ They will tell you whether you are required to have a study partner, and what is expected of your study partner. A study partner is usually a relative or a friend of the participant.
- ▷ They'll probably also remind you that some potential participants in the study may be screened out after two or three months of study-related assessments. This is because some people will not fit the needs of the study and how the medication is thought to work. People who are screened out may still receive valuable information from the assessments they have completed.

You should ask any question you would like. The research team's representative should be able to answer them or get you answers. Your medical history and other information you provide is confidential.

One question you may want to ask is what information you will be given about your own health condition. Some studies provide written information about certain results, like blood tests. Sometimes, a doctor will sit down and discuss what tests show about your brain health. Other studies provide much less information.

Sharing information with you and answering your questions are part of the informed consent process. You'll be asked to sign an informed consent form to show that you understand why the research is being conducted, the risks, including potential side effects, and benefits. The informed consent form is not a contract. You have the right to leave the trial at any time, for any reason, if you choose.



THE SCREENING PERIOD

All studies have rules that indicate who can participate and who cannot. In the initial screening, a member of the research team checks to see if you meet the trial's criteria for age, sex, race or ethnicity, and general health history.

If you do, and you're admitted into the trial, there will be a second screening period. Generally, that lasts 60 to 90 days for Alzheimer's studies. During that time, researchers conduct a series of diagnostic tests to determine who will continue with the trial.

One of the benefits of being in a clinical trial is that they usually involve extensive screening of your brain, body, memory and thinking abilities so researchers can see if they change over time. You may get a copy of that information, even if you aren't selected to participate in the trial. Some tests that may be part of the screening process can cost thousands of dollars. They are not always covered by insurance, but qualified participants in clinical trials often get the results for free. This can help you better understand your health situation, and notice if it changes over time. You won't have to pay to participate in a clinical trial. Some pay participants a stipend.

What to Expect When You Participate in a Clinical Trial



TESTS COMMONLY USED IN ALZHEIMER'S CLINICAL TRIALS

There are two types of proteins that cause brain cells to stop functioning, lose connections with other brain cells, and die. Amyloid plaques build up over time and interrupt the messages conducted from one part of the brain to another. Neurofibrillary tangles are snarls of proteins that systematically destroy brain cells from the inside.

Researchers use a few different tools to study those conditions:

- ▷ Magnetic resonance imaging (MRI) scans are used to get a structural view of the brain. An MRI scan uses a magnetic field to determine if any structural or blood flow issue could be causing memory problems, rather than Alzheimer's.
- ▷ Positron emission tomography (PET) measures the level of metabolic activity in the brain.
- ▷ An amyloid PET scan is a specialized PET scan that can detect amyloid plaque build-up in the brain. It can detect amyloid plaque build-up even before a person experiences any memory loss. Getting an amyloid PET scan is a benefit of participation in some trials because it often is not covered by insurance and can cost thousands of dollars.
- ▷ Special PET scans measure brain glucose metabolism, which reflects activity between brain cells and has a characteristic pattern in people with Alzheimer's.
- ▷ Computed tomography (CT) scans use X-ray slices to create images of the brain from different angles. Some studies offer CT scans for people who can't undergo an MRI. Some trials don't use CT scans at all.

- ▷ A lumbar puncture (LP) is procedure to draw fluid from the spinal column and detect the level of amyloid and certain proteins in it.
- ▷ Lab work – tests on blood or other bodily fluids – are used to rule out other causes of memory loss.
- ▷ Cognitive rating scales are tests to measure the extent of memory loss and cognitive impairment. Other rating scales measure behavior, mood, and how well you perform daily activities.

PLACEBOS

In many clinical trials, some participants are given a placebo. A placebo looks like the study medication but doesn't have any active qualities. Some people are given the placebo instead of the treatment being tested to determine if there are any differences in the outcomes for the two groups. In some studies, the chance of getting a placebo is less than getting the treatment. Like the treatment group, people who receive the placebo also get frequent, high standard of care visits with trained medical staff. Often, people on placebo see improvement too. Keep in mind – the only way to get treatment being studied is to participate in a clinical trial.

What to Expect When You Participate in a Clinical Trial

STUDY METHODS

Blinded studies are designed to prevent the researchers and study participants from influencing the results. In single-blind studies, participants aren't told what medication they are being given, but the medical team giving the treatment knows. In double-blind studies, neither the participants nor the medical team giving the treatment know what medication specific participants are being given. However, if it is medically necessary, it is possible to find out what treatment a participant has received.

Some clinical trials are “open label” trials. During the trial period, the participants do not know whether they are receiving the medication or the placebo. After the trial period, participants who had been given the placebo receive the active medication during an extension period, unless it has been evaluated as ineffective.

HOW DO I KNOW A CLINICAL TRIAL IS SAFE?

Researchers want their trials to be safe. They also are required to follow strict rules to make sure participants are safe. Each Alzheimer's clinical trial in the U.S. is approved and monitored by a committee of doctors, scientists and other people with expertise in research ethics and law – known as an Institutional Review Board (IRB) – to ensure the risks are reduced and are outweighed by potential benefits. The IRB reviews the trial before it starts and as it proceeds to protect participants' rights and safety.

STUDY PARTNERS

Today, many clinical trials for Alzheimer's disease want the participant to have a study partner. The study partner may be someone who knows and interacts with the study participant – the person with Alzheimer's – on a regular basis. The study partner is often the person's main caregiver (care partner), but not always.

If you are interested in participating in an Alzheimer's clinical trial but you don't know who your study partner would be, you should still sign up. The people running the trial may be able to help you connect with a study partner.

The study partner helps the participant in the trial:

- ▷ Reminding the participant about appointments
- ▷ Helping with transportation to and from the trial location
- ▷ Describing the benefits and risks of participating in the trial.

The study partner also reports her or his observations of the participant in daily activities to the researchers. Information from study partners is important. It helps researchers determine if the trial has been successful.

People who are study partners for Alzheimer's clinical trials help their friend or relative with Alzheimer's get advanced care and expert medical opinions, and access to the best diagnostic tools. The information from the trial may help people with Alzheimer's and their caregivers in the future. It may even lead to ways to prevent or treat the disease.

The Phases of Clinical Trials

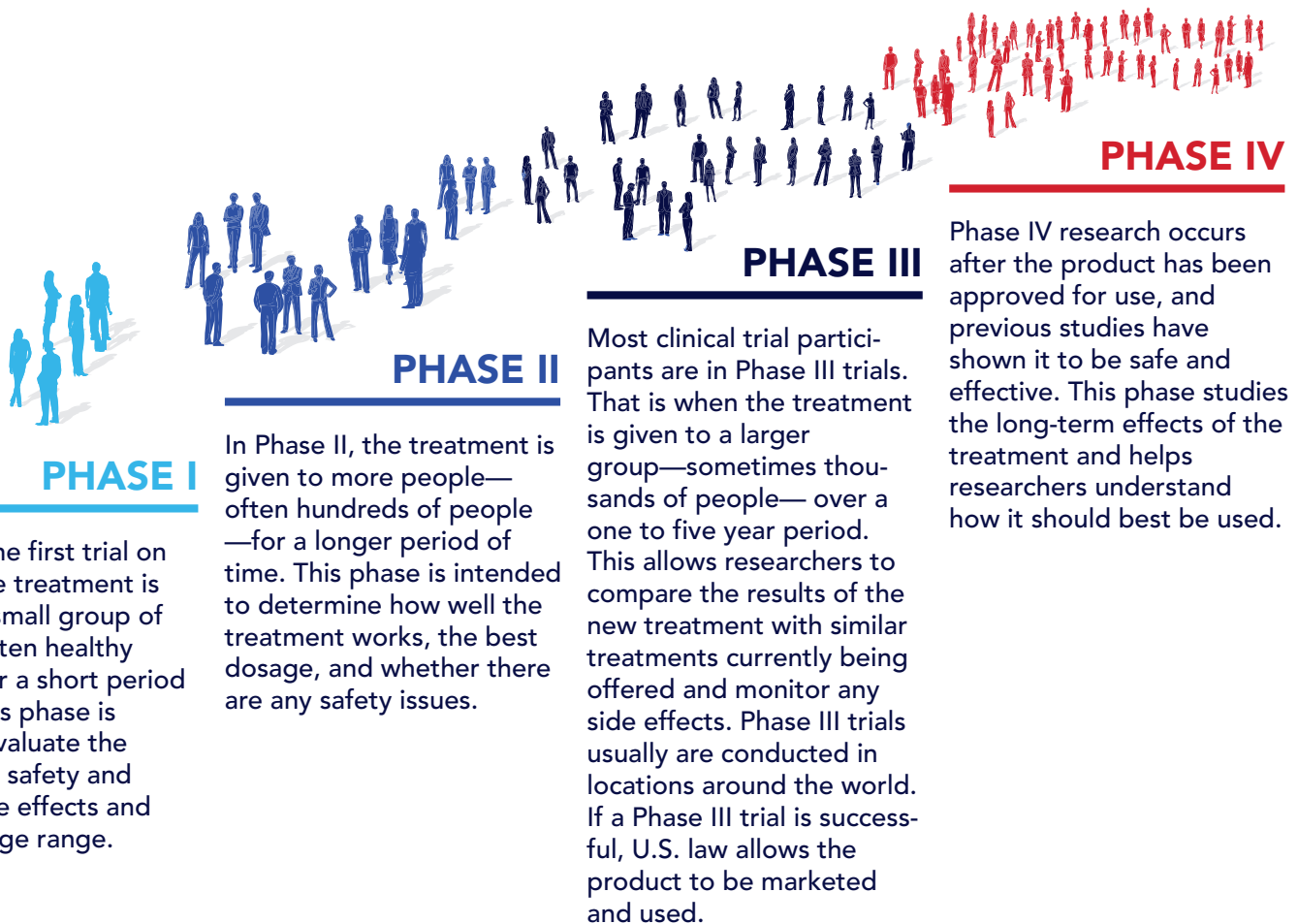
HOW NEW TREATMENTS ARE DEVELOPED AND APPROVED

Before a medication or treatment can be offered to the public, the FDA requires clinical trials to demonstrate that it is safe and effective.

First, researchers at a drug or biotechnology company have **an idea** for a promising medication based on existing science. They'll create the chemical compound that they want to test.

Next, the investigational product goes through **preclinical testing** on animals to determine if it is reasonably safe to use in people, and in what amounts it should be used for testing on people.

Then there are **four phases** of research on people:



RESPECT

Geri Taylor

Speaker, leader, participant in an Alzheimer's clinical trial



Late in her career as a health care administrator, Geri Taylor experienced moments where her mind became foggy. Leading a staff meeting, she lost her train of thought. Another time, she got off the New York City subway at 14th Street but didn't know why she was there. She could no longer prepare a meal and hold a conversation at the same time.

But when she looked into the mirror one morning and didn't recognize her own face, she had to accept the truth. She confided to her husband, Jim, and made an appointment with a neurologist. The doctor diagnosed her with mild cognitive impairment, a common precursor to Alzheimer's. It was late 2012 and she was 69 years old.

"I was a senior executive in the long-term care field, and I developed programs that helped tens of thousands of people," says Geri. "But my diagnosis was the beginning of accepting that a new view of myself and my life was necessary. Now I think and plan for tasks that were once automatic."

After Jim read a newspaper article about an early-stage clinical trial for an experimental medication, Geri searched the internet and found that the trial used a center at Yale New Haven Hospital in Connecticut. Geri enrolled in testing, which determined that she had amyloid plaque build-up in her brain. She has participated in the trial for three years, and feels she has received excellent care from the research team.

Geri gets a monthly infusion of the drug in Connecticut. Sometimes the Taylors visit Florida. When they do, Geri can get her infusion at a nearby clinic. Early analysis of the drug Geri takes in the trial shows promise in slowing cognitive decline and removing plaque from the brain.

"I believe that we who have Alzheimer's have a responsibility to ourselves, family, and society," says Geri. "People currently in trials are an underutilized asset and, with training, can provide valuable assistance for clinical trial recruitment. Talking to people and letting them see the face, good intentions, and life of a person with the disease will go a very long way to breaking down stigma and fear."

RESPECT

Geri Taylor

Speaker, leader, participant in an Alzheimer's clinical trial



When she was first diagnosed, some people told Geri not to tell anyone, or she would lose friends, but she didn't like the idea of hiding what was happening. Later, after she had told her family and friends, Geri and Jim were invited to talk to a church group about their experience with Alzheimer's. She gave tips on how to communicate with someone with Alzheimer's: Focus on one subject; don't ask multiple questions at once. People appreciated her advice, laughed at some of the details, and gave a long ovation when the presentation was over.

Since then, Geri and Jim have given many presentations about their experience living with Alzheimer's. They have talked to church members, Alzheimer's support groups, universities, and participants at events like Alzheimer's walks. They share tips for living with the disease and being a caregiver, and they talk about Geri's positive experience as a participant in a clinical trial. They've reached thousands of people.

GERI TAYLOR'S PRACTICES FOR LIVING WITH ALZHEIMER'S

- ▷ **Focus on one task at a time.** When I'm walking, I talk only when necessary.
- ▷ **Use your smart phone.** I keep mine with me at all times. I rely on the calendar and notes. And the people finder app can help my husband find me if I get lost.
- ▷ **Keep things as neat as possible.** I reduced the number of things around me.
- ▷ **Walk and take taxis or trains as a substitute for driving.** That allows me to get around the city.
- ▷ **Take yoga or exercise classes.** These activities improve my balance.
- ▷ **Keep reading.** Choose books with straight-line plots and fewer characters.
- ▷ **Take responsibility for initiating connections with friends and family.** I let them know I love them, and I've found they feel more comfortable letting me know they love me.
- ▷ **Every day, reflect on how you take care of yourself and live with others.** I draw strength and connection from being involved with activities, support groups, and walks for people with Alzheimer's.

STRENGTH

Daisy Duarte

Caregiver, fighter, participant in an Alzheimer's clinical trial



Daisy Duarte of Springfield, MO is a full-time caregiver for her mother Sonia, who has early-onset Alzheimer's. After Sonia moved in with her, Daisy had to close her successful sports bar. Now she gets hourly work when she can.

Sonia's Alzheimer's is caused by a rare form of the disease caused by a genetic mutation that runs in families. Genetic testing shows that Daisy has the same mutation. Unless a cure is found, Daisy can expect to get the disease.

Daisy signed up for a clinical trial of a new experimental drug being studied by researchers at the Washington University School of Medicine in St. Louis. Every month, a nurse comes to Daisy's house to give her two injections. The drug is designed to stop Alzheimer's before Daisy begins to lose her memory. Starting treatment early is a new approach that researchers believe holds promise. It will be years before we know if it is a success.

"I feel that I'm at least doing something. I'm not just sitting there moping because I have a genetic mutation," says Daisy. "I'm standing up to the disease."

Daisy also is an advocate for Latinos with Alzheimer's, and everyone fighting the disease. More than 1.8 million Latino family members care for someone living with Alzheimer's or dementia.

Says Daisy, "The majority are daughters like me, providing high-stress, around-the-clock care for loved ones who often don't remember who we are and too often cannot dress, feed or bathe themselves. It's a tough job that we take on with love, a sense of duty and honor, but it's a job that we need help with. Alzheimer's funding should be a national priority. We need a cure."

"It hurts to see someone that's been so independent, that's raised three kids, deteriorate year after year after year," Daisy says about her mom. "It's an emotional roller coaster. I get exhausted a lot."

CARING

Ida Manning

Honoring her Mother by Volunteering for Clinical Trials



Ida Manning’s mother, Basia, was a strong person. She survived slave labor camps in Poland and Germany in World War II. Basia and her husband moved to Chicago and raised three daughters. When Ida’s father grew ill in old age, Basia continued to care for him. That’s when Alzheimer’s disease began to rob Basia of her memory and ability to think clearly.

After her husband’s death, Basia retreated to her bed, and rarely left it. Near the end of her life she couldn’t walk or talk or communicate – except by singing. Ida would sing familiar songs that Basia had taught her in Hebrew, Yiddish, Polish or German and Basia would sing along. At the very end, she would hum.

Toward the end of her life, Basia wasn’t talking at all. Then one night – out of the blue – Basia told Ida, “You look really good tonight.” They had a back and forth conversation for about an hour where Basia could answer questions about what made her comfortable and family news. Basia told Ida she knew that she loved her. This one hour of conversation amazed Ida, even though Basia’s words were quite simple.

Those moments were a gift, and that’s when Ida knew she had to do something to fight Alzheimer’s disease. That’s what led her to become a research volunteer. Ida says, “I don’t have millions of dollars to give but I can still contribute by participating in research.”

Ida has been in two studies at Great Lakes Clinical Trials in Chicago. “I felt appreciated as a research participant,” says Ida. “From the minute I walked in the door, the research team was welcoming.”

First, Ida was in a double-blind study of a medication that involved lots of intense memory studies.

The second study Ida was in involved a genetic test to find people with the APOE4 gene. “You have to have at least one copy of the gene to be in the study,” she explains. “I learned I have one copy of the APOE4 gene so I have a 20-25% lifetime chance of getting Alzheimer’s. That gave me a sense of relief because I know where I stand.”

The next step in the study was an MRI and a PET scan. After those, they dropped Ida from the study because she didn’t have amyloid plaque build-up in her brain. “So I learned I’m not as much at risk as I thought I was,” she says. “Now I know it would take another 10-15 years to build up enough amyloid in my brain to cause symptoms. That made me really happy, even though I miss not being in a clinical trial now. I definitely would do another one.”

Ida encourages other people to participate in Alzheimer’s research, saying, “We’re close to a breakthrough, but we need more research volunteers to speed the pace of clinical trials.”

PERSISTENT

Andres Martin

Father, Husband, Marine, Entrepreneur and Participant in Alzheimer's Clinical Research



Andres Martin's family believes both his grandfather and father had early-onset Alzheimer's disease, which caused their minds to decline significantly in their 40s. But it wasn't diagnosed by doctors because who believed the men were "too young." Andres' father was 51 years old when he died in 2011.

In 2017, while Andres was stationed with the U.S. Marines in Hawaii, he read an article about the Jalisco genetic mutation, which dramatically raises the risk for early-onset Alzheimer's in people that have it. It affects people descended from a common ancestor in the Mexican state of Jalisco. Andres contacted the doctor who wrote the article and took a genetic test in August 2017. It showed he has the Jalisco gene mutation.

"The day I received my genetic test results was one of the most emotional days of my life, due to a positive diagnosis of a terminal disease," says Andres. "I felt sorry for myself that day, but I was not going to let it control the rest of my healthy life. My beautiful wife and daughter keep me grounded. I will never let Alzheimer's take over my life."

"My biggest fear in life is that my baby Alexis could be carrying the gene," Andres says. "At 20 months old, she has no idea what the Jalisco mutation is and how it could affect her life. One thing she will remember is my commitment to helping find a cure so that she will not have to suffer like daddy and grandpa."

Alzheimer's disease is forcing Andres to give up his dream career: "I remember the day my father and I walked into a donut shop at the age of 9. Inside the shop was a Blue Angels poster and from that day, I knew that I wanted to be a military pilot. My dream was fulfilled in 2014 when I received my wings of gold. Three years later, I made a decision to terminate my flying career due to my diagnosis. My dream career was killing me slowly, due to sleep deprivation and

PERSISTENT

Andres Martin

Father, Husband, Marine, Entrepreneur and Participant in Alzheimer's Clinical Research



stress severely accelerating my condition. It became difficult for me to memorize complex numbers and procedures I used to be able to memorize two years before. Now I was not able in the same capacity as before. When the facts were presented to me, the decision to give up my dream was easy.”

Andres is participating in the Dominantly Inherited Alzheimer's Network (DIAN) long-term observational study of people at risk for early-onset Alzheimer's, led by Washington University School of Medicine in St. Louis. Some of the volunteers in the study participate in clinical trials for specific medications.

Andres advice to the people he calls his “fellow Genetic Mutants” is to try to live a normal life. “We already have a thing trying to kill us – Alzheimer's disease. Let's not assist it by letting it completely control our mental health. I have bad days and good days. Anxiety and sleep deprivation might beat me some days, but I don't let it control my life!”

“I personally see in order to find a cure, doctors and patients need to work as a team,” Andres explains. “The government has decided to invest money on Alzheimer's research, but billions of dollars for researchers without medical trial participants gets us nowhere. For me, participating in a clinical trial was a no brainer, no pun intended, because of Alexis. My main goal in life is to save my baby's life. I do not have the right to complain about doctors not having a cure for Alzheimer's, if I'm not actively participating in research to find a cure.”

Questions and Answers About Alzheimer's Disease

Alzheimer's disease, dementia, and mild cognitive impairment – What are they?

Alzheimer's disease is the most common form of dementia, a progressive brain condition that slowly destroys memories and thinking skills. Researchers believe Alzheimer's is caused by protein molecules that form plaques in the brain that stick to brain cells or protein molecules that tangle within brain cells. Both types of proteins injure brain cells and impair their functioning.

Alzheimer's often starts many years before symptoms appear. The first sign in the development of Alzheimer's is mild cognitive impairment (MCI), modest changes in memory and thinking ability, usually not significant enough to affect work or personal relationships.

The next stage of Alzheimer's, mild dementia, interferes with some, but not all, daily activities. People with mild dementia may get lost occasionally, have trouble making financial decisions or paying bills, or struggle remembering the names of people they just met.

The brain functioning of people with Alzheimer's tends to deteriorate over time. People with moderate dementia experience more memory loss. They may also have trouble expressing themselves or understanding others, recognizing family or friends, carrying out multi-step processes like getting dressed, or knowing what to do in new situations. One person's symptoms may vary from day to day or at different times.

People with severe dementia are extremely limited by the disease. They may not be able to communicate at all, and they depend on others for their care.

About 5.7 million Americans
are living with Alzheimer's

and there are

16 million family caregivers.

Health care, long-term care, and hospice care for people with Alzheimer and dementia
cost about \$277 billion in 2018.

Alzheimer's disease is underdiagnosed and underreported. Many people with Alzheimer's may not know they have it because they have not been diagnosed by a doctor.

Doctors prescribe medications to treat the memory loss associated with Alzheimer's. There is no cure for the underlying disease, but there are clinical trials studying the effectiveness of new treatments for the disease.

Clinical trials are medical research or drug development tests to evaluate new ways to prevent, treat or detect disease. Before a drug or treatment can be offered to the public, the law requires clinical trials to demonstrate that it is safe and effective.

Questions and Answers About Alzheimer's Disease

How do I know if I have Alzheimer's disease?

As we grow older, it's normal for our cognitive abilities to change. That includes our ability to access memories, gain knowledge, and understand things.

Typical age-related changes include:

- ▷ Forgetting which day it is and remembering later
- ▷ Sometimes forgetting which word to use
- ▷ Losing things from time to time
- ▷ Missing an occasional monthly payment
- ▷ Making a bad decision once in a while.

Those experiences are a normal part of aging. Alzheimer's is different.

For people with Alzheimer's disease, memory loss worsens over time until it interferes with most aspects of daily living. A person with Alzheimer's may:

- ▷ Get lost or become confused – even in familiar settings
- ▷ Stumble over routine tasks such as preparing meals, doing laundry, and other household chores
- ▷ Struggle to recognize people and name objects
- ▷ Have trouble handling money
- ▷ Experience personality and behavior changes.

For most people, Alzheimer's disease appears after age 65. For about five percent of people with the disease, it appears before age 65. That's called early-onset Alzheimer's.

How is Alzheimer's disease diagnosed?

If you think you might have Alzheimer's or another form of dementia, you should discuss it with a doctor. To diagnose Alzheimer's, your doctor may ask you, and a family member or friend, about your overall

health, ability to carry out daily activities, and changes in behavior and personality. They may conduct tests of memory, problem solving, attention, counting, and language, as well as lab work, like blood and urine tests. And they may do brain scans, like MRI, PET, or CT scans.

Your doctor will try to find out if changes in your memory or thinking may be due to another cause, like a stroke, tumor, Parkinson's disease, sleep problems, side effects of medication, an infection, or a non-Alzheimer's dementia. Some of those conditions are treatable and possibly reversible.

Does it make a difference if I get diagnosed now, or wait until later?

Yes! Early diagnosis may have some advantages. If you are diagnosed with Alzheimer's early, you may be prescribed medications that can improve your memory or thinking, especially in the early and mild stages of the disease. And early diagnosis may give you the ability to join a clinical trial when the benefits are most effective. Another benefit of early diagnosis is you can learn about the disease and make plans for adjusting to it while your mind is still strong. You can choose what information about your diagnosis you want to share with family and friends, and when and how you're going to do that. You also can plan ahead. You may want to plan for future living arrangements, or the possibility of a long-term illness.

How is Alzheimer's currently treated?

There are no approved drugs or other treatments that will cure Alzheimer's, prevent it, or delay its onset. However, there are drugs approved by the U.S. Food and Drug Administration to treat the symptoms of dementia. These include Aricept, Razadyne, Exelon, Namenda, and Namzaric. There are generic versions of most of these. These drugs work to improve the functioning of existing brain cells, but they do not stop the underlying disease. They may improve day-to-day cognition and memory for a while, but the underlying disease can worsen at the same time.

Questions and Answers About Alzheimer's Disease

What causes Alzheimer's?

There are two types of proteins that can cause neurons (brain cells) to stop functioning, lose connections with other neurons, and die.

- ▷ Neuritic amyloid plaques are made up of “sticky” misfolded proteins and injured nerve cells. These plaques form around neurons, and interrupt the messages conducted from one part of the brain to another.
- ▷ Neurofibrillary tangles are snarls of tau proteins that form within neurons. They systematically destroy brain cells from the inside.

You don't need to understand the science of Alzheimer's to participate in a clinical trial and make a difference in curing the disease.

What treatments are researchers studying?

Many clinical trials for Alzheimer's are for one of two major classes of medication:

- ▷ Monoclonal antibodies are molecules that can target and attach to a specific substance in the brain. That substance may be the plaques or tangles of proteins associated with Alzheimer's. The antibodies tell the body's immune system to clear away the molecule, along with the harmful substance attached to it. Monoclonal antibodies are administered through IV infusions, typically monthly.
- ▷ BACE inhibitors target beta-amyloid cleaving enzymes (BACE). This type of enzyme incorrectly breaks up the amyloid precursor proteins in the brain, resulting in sticky plaque-forming fragments. BACE inhibitors limit the activity of that enzyme, reducing the amount of incorrectly degraded protein and the amount of plaque that builds up. BACE inhibitors are administered as pills.

Monoclonal antibodies and BACE inhibitors are currently available only to participants in clinical trials.

Other clinical trials use established medications in new combinations to try to make them more effective. A few trials use strategies other than targeting amyloid precursor proteins. Some trials are focused on interventions that don't involve medicines.

Can I still see my regular doctor if I participate in a clinical trial?

Generally, a trial volunteer continues to see his or her doctor regularly, and tells the doctor about the clinical trial. Some volunteers show a copy of the informed consent document to their primary doctor.

Will researchers give information to my regular doctor?

You can ask the researchers if they can send your regular doctor information like your lab results. Some clinical trials may send some findings about your health to your doctor. Others don't allow distribution of study records until the trial is finished. If a health issue happens during the trial, researchers may tell your doctor, if you have given permission.

Will participating in a clinical trial affect my Medicare, Medicaid, or other health insurance?

No, it will not affect your health insurance. Under federal law, insurance carriers must cover the routine costs of people taking part in clinical trials, and they can not limit or drop your coverage because you participate in one.

Questions and Answers About Alzheimer's Disease

Where else can I get my questions answered?

The Alzheimer's Disease Education and Referral (ADEAR) Center is a government service from the National Institutes of Health. ADEAR Center staff can answer questions about Alzheimer's, send you free publications, and give you information about clinical trials. You can call them toll-free at 1-800-438-4380, 8:30am to 5:00pm ET, Monday to Friday, or email adear@nia.nih.gov.

ADEAR also offers materials in Spanish and has Spanish-speaking staff at 1-800-438-4380.

Who sponsors clinical trials?

Clinical trials for Alzheimer's research are often sponsored by respected medical schools or hospitals, private companies that develop and sell medications, or government agencies like the National Institutes of Health, or a combination of those.

Can I participate in more than one clinical trial at once?

Generally, you can only participate in one trial that provides a treatment at a time. However, you may be able to participate in an additional observational study while you also are in a trial with a treatment.

What should I know about direct-to-consumer genetic tests for Alzheimer's?

A genetic test can give an indication of whether a person has increased risk for Alzheimer's, but it can't tell for certain whether or not a person will get the disease. Researchers believe that multiple genes and lifestyle factors – like diet, exercise and sleep – all play a role.

The FDA has allowed at least one direct-to-consumer genetic testing company, 23andMe, to offer a test for Alzheimer's risk. It analyzes the APOE gene, which is associated with the likelihood of getting late-onset Alzheimer's, the most common form of the disease. The test shows if a person has zero, one or two copies of the e4 allele on the APOE gene. People with zero copies of the e4 allele have the same risk as the general population; people with one e4 allele have an increased risk of developing Alzheimer's, and people with two e4 alleles have an even greater risk.

Because there is no proven way to prevent or cure Alzheimer's, the National Institute on Aging and other groups recommend against genetic testing except in a research setting like a clinical trial. A person thinking of taking a genetic test that may show risk for Alzheimer's is advised to talk to his or her doctor first. People who take a direct-to-consumer genetic test and learn that they are at increased risk for Alzheimer's may be candidates for clinical trials. Clinical trials will often provide information about brain health or treatments intended to prevent or delay symptoms.

You can use the ZIP code locator at [UsAgainstAlzheimer.org/research](https://www.usagainstalzheimer.org/research) to contact a clinical trial site near you.

Talking About Alzheimer's Clinical Trials: You Can Make A Difference

Participating in an Alzheimer's clinical trial is one way people with the disease can make a choice to exert power over it, and embrace hope for the future.

You can use the information in this toolkit to spread the word in your community about how important Alzheimer's clinical trials are, and to get people to visit UsAgainstAlzheimers.org/research to learn more.

Here are some things you can do:

- ▷ **Have a conversation with someone one-on-one or in a small group.** If you know someone who has Alzheimer's or is a caregiver, talk to them about participating in a clinical trial, and your own experience.
- ▷ **Give a short presentation at a community meeting or event.** This toolkit has presentation slides, speaker notes, and videos to help you – even if you're not an experienced speaker.
- ▷ **Distribute information about clinical trials.** You can share UsAgainstAlzheimer's Curing Alzheimer's: Clinical Trials are the Key, through your library, church, senior center, health provider, or another local organization.
- ▷ **Use social media.** We've got messages and images you can post or adapt, or you can use the messages in the brochure to write your own.
- ▷ **Talk to the local media.** You've got an interesting story to tell, and important information to share about how clinical trials are the key to curing Alzheimer's. This toolkit has advice about how to reach out to the local media to suggest they cover it.

HAVE A CONVERSATION WITH SOMEONE ABOUT CLINICAL TRIALS

Are you participating in a clinical trial now, or have you in the past? Maybe you're a caregiver for someone who was a participant? If so, you know more about clinical trials than most people. In fact, you're an expert! That means there's more you can do to help accelerate a cure for Alzheimer's. You can talk to someone who has the disease about your experience, clinical trials, and how important it is to participate in one.

- ▷ **Initiate a conversation.** People value the opinions of their friends, and they often look to peers with experience for advice. The best way to start a one-on-one conversation is to ask if the person would like to hear about your experience with a clinical trial and how important they are for accelerating a cure. The brochure, *Curing Alzheimer's: Clinical Trials are the Key*, includes additional information you can use to help someone understand the importance of clinical trials for accelerating a cure.
- ▷ **Tell your story.** People learn best from personal stories. If you or someone you know has Alzheimer's, you've got a very interesting story to tell. Share what you're comfortable sharing, including your experience with a clinical trial. Is there anything you know now that you wish someone had told you sooner?

Talking About Alzheimer's Clinical Trials: You Can Make A Difference

- ▷ **Ask the person to go to [UsAgainstAlzheimers.org/research](https://www.usagainstalzheimers.org/research) for more information.** Suggest that your friend can get information about specific clinical trials from [UsAgainstAlzheimers.org/research](https://www.usagainstalzheimers.org/research) or by calling the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380, and that they should ask their doctor about participating in a trial.
- ▷ **Be patient.** Don't press anyone to listen to your experience with Alzheimer's or clinical trials if they don't want to. They may ask you for more information in the future, or they may not – and that's OK.
- ▷ **Talk to your regular doctor.** Tell your doctor about your experience with an Alzheimer's clinical trial. Drop off information about the trial site at the doctor's office.

GIVE A SHORT PRESENTATION AT A COMMUNITY MEETING

One way to spread the word about the importance of clinical trials for accelerating an Alzheimer's cure is to give a presentation to a group. It might be a club or community service organization, a veterans service group, a senior center, a medical facility, or a religious organization. You can put it on the agenda of an already scheduled gathering, or ask for a special meeting to talk about this topic. On the [UsAgainstAlzheimer's](https://www.usagainstalzheimers.org) website, there are presentation slides and notes you can use. Going through the slides takes about 10 minutes. You also can use a short video. You may want to include a short question and answer session. We've included some common questions and answers in this guide.

Here are a few things to consider before your presentation.

- ▷ If you have Alzheimer's, or you are presenting with someone who does, consider comfort. For example, someone with Alzheimer's may be

more comfortable sitting than standing while speaking. Also, if there are questions, it is best to have a system to take them one at a time.

- ▷ It is important to encourage people to ask questions and accept all questions without making anyone feel like their question was not worth asking. The people who leave presentations and then participate in a clinical trial tend to be the people who ask questions.
- ▷ Consider the size of your audience, and what they might be interested in learning about clinical trials.
- ▷ Know the start time of your presentation, and how long you are expected to speak. Don't go over time.
- ▷ It helps to have a checklist of things you have to bring to the presentation. Think ahead about set-up needs. If you want to show slides or a video, you'll need a computer hooked up to a screen or projector. It is a good idea to download any slides or videos to the computer in advance.
- ▷ Print or prepare any materials you plan to leave behind with your audience.
- ▷ Think about the main point of your presentation – to encourage people with Alzheimer's or dementia to visit [UsAgainstAlzheimers.org/research](https://www.usagainstalzheimers.org/research) or call the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380 and contact a site to learn more about participating in a clinical trial. Make that point a few times. Friends, family, and caregivers of people with Alzheimer's are important audiences.
- ▷ Practice by rehearsing out loud, timing your presentation, and thinking about questions that may come up and how you will answer them.

Talking About Alzheimer's Clinical Trials: You Can Make A Difference

Consider making your presentation interactive. You don't have to use slides or notes to guide it. Starting can be as simple as showing a video and asking for reactions. You can use this guide to help prepare for questions. You can find more information about clinical trials at UsAgainstAlzheimers.org/research.

DISTRIBUTE INFORMATION ABOUT CLINICAL TRIALS

Another way to teach people about clinical trials is to give them *Curing Alzheimer's: Clinical Trials are the Key*. You can offer copies to your local library, senior or community center. Or you can write a blurb about clinical trials and Alzheimer's for your community newsletter or the bulletin at your place of worship. Please copy from the brochure or the UsAgainstAlzheimers.org site. You have our permission.

USE SOCIAL MEDIA

When you post to your social media accounts – like Facebook, Twitter, Instagram, Snapchat, LinkedIn or others – about the benefits of clinical trials, you can help people decide to participate. Keep these points in mind:

- ▶ **Show people living with Alzheimer's in a positive light.** After all, it's their participation that gets us closer to a cure.
- ▶ **Share your experience.** If you are a participant in a clinical trial, ask the site if you can take some pictures of yourself there to help people better understand what it is like and why they might want to participate in a trial.
- ▶ **Include a request for people to take action.** That request could be to learn about a specific clinical trial, to visit UsAgainstAlzheimers.org/research or call the Alzheimer's Disease and related Dementias Education and Referral Center (ADEAR) at 800-438-4380 to find a nearby trial site, or for your friends to share information about clinical trials with people in their own networks.

- ▶ **Use hashtags and handles.** Hashtags like #StopAlz, #Alzheimers or #WeWontWait make it easier for people to find your posts. Using the "@" sign before someone's Twitter handle or Facebook username will "tag" the person and notify him or her of your tweet or Facebook post.

Here are some sample shareable social media posts, hashtags, sample tweets and social media handles you can use to encourage people to learn more about clinical trials, and participate in them.



UsAgainstAlzheimer's @UsAgainstAlz
Without clinical trials, there can be no better treatments, no prevention and no cure for #Alzheimers disease. Check out the new #ClinicalTrials toolkit from @UsAgainstAlz to learn more about participating in #Alz research. <https://www.usagainstalzheimers.org/research>

UsAgainstAlzheimer's @UsAgainstAlz
One of the keys to curing #Alzheimers is enrolling people in the early stages of the disease into #ClinicalTrials. That's how we'll find out which treatments are most effective at slowing, stopping, or preventing the disease. Learn more from @UsAgainstAlz. <https://www.usagainstalzheimers.org/research>

Talking About Alzheimer's Clinical Trials: You Can Make A Difference



UsAgainstAlzheimer's
#Alzheimers researchers need more people to participate in #ClinicalTrials. Without clinical trials, there can be no better treatments, no prevention and no cure for #Alzheimers disease. You can find Alzheimer's or dementia clinical trial or study sites near you by visiting <https://www.usagainstalzheimers.org/research> and entering your ZIP code.

TALK TO THE LOCAL MEDIA

Your local media can help you spread the word about how participation in clinical trials is the key to solving Alzheimer's. Sharing your personal story may help them decide to run a piece on this important topic.

Email a reporter for a local newspapers, blog, or TV news show, or the host of a radio show. If there's a reporter who covers health care, science, or aging issues, that's probably a good person to contact. Ask if they are interested in a story on clinical trials for Alzheimer's treatments and how important they are in the search for a cure. Share a sentence or two about your personal story, and let them know you can provide facts from UsAgainstAlzheimer's and other sources.

If there is national or regional news about Alzheimer's – like if a celebrity shares a diagnosis, or promising research is announced – local reporters might be particularly interested in your story, too. Use that opportunity to follow up with your local media and offer your story and perspective.



UsAgainstAlzheimer's
Did you know that researchers need people who don't have #Alzheimers to participate in #ClinicalTrials? Alzheimer's starts to form in the brain up to 20 years before symptoms appear, so researchers need to study healthy people to see how their brains change over time. Learn More: <https://www.usagainstalzheimers.org/research>

UsAgainstAlzheimer's would like to thank the members of its Clinical Trials Awareness Toolkit Steering Committee:

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