

The Importance of Participating in Clinical Trials in Alzheimer's Disease

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First and foremost...

- Clinical trials and studies are a **partnership** between researchers and volunteer participants, who work **together** to answer questions in a controlled, scientific way.
- Today, at least 70,000 volunteers are urgently needed to participate in more than 150 active studies in the US testing ways to understand, treat, prevent, or cure Alzheimer's disease. All kinds of people are needed!

Types of clinical research

- Natural history studies- follow how diseases progress.
- Prevention trials- look for ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Better approaches may include medicines, vaccines, or lifestyle changes, among other things.
- Screening trials- test the best way to detect certain diseases.

Types of clinical research

- Diagnostic trials - determine better tests or procedures for diagnosing a particular disease.
- Treatment trials - test new drugs, combinations of drugs, or other treatments in a specific disease.
- Instrument trials – validate the usefulness of rating scales or cognitive tests.
- Quality of life trials - explore ways to improve the comfort and quality of life of people with a chronic illness.

What is a Clinical Trial?

- Clinical trials involve testing a new medication or therapy in a series of steps (or phases) to treat a specific illness or condition.
- New drugs must successfully complete a three-phase process before being approved for use by the U.S. Food and Drug Administration (FDA).
- There are currently over 70 treatments for AD being studied.

Phases of clinical trials

- **Phase I** trials: Researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety and identify side effects.
- **Phase II** trials: The treatment is administered in a larger group of people to determine its effectiveness and to further evaluate its safety.

Phases of clinical trials

- **Phase III** trials: treatment administered to large groups of people to confirm effectiveness, monitor side effects, and compare with standard or equivalent treatments
- **Phase IV** trials: After a drug is approved by the FDA and made available to the public, researchers track its safety, risks, benefits, and optimal use.

Steps in Clinical Trial Participation

- Study staff explain the trial in detail and gather basic information about you to make sure you meet basic eligibility.
- Once you have had all your questions answered and agree to participate, you sign an informed consent form.
- You are screened with cognitive tests, physical examination, lab tests, and brain imaging to make sure you qualify for the trial.

Steps in Clinical Trial Participation

- If you meet criteria to enter, you undergo a **baseline** visit. This serves as a comparison point.
- You are randomly assigned to a treatment or control group (**placebo**). This is usually **double blinded**, so neither you nor the research team will know to which group you are assigned.
- You and your family members follow the trial procedures and report any issues or concerns to researchers during the course of the study.

Most Alzheimer's trials will

- Limit participants to a certain age range.
- Require participants to be in a certain stage .
- Not allow cognitive disorders other than the one being studied.
- Require that medications & health problems be stable for a certain period of time before screening.
- Not permit use of certain medications.
- Require participation of an informant, caregiver, or study partner.

Why Should I Participate in a Clinical Trial?

- Help others, including future family members, who may be at risk for Alzheimer's disease.
- Receive regular & careful monitoring by medical professionals.
- Test new treatments that may work better than what is currently available.
- Access to medical tests that insurance may not cover.

Why Should I Participate?

- 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/inconclusive results.

Questions to consider

- What is the purpose of the study?
- What tests and treatments are involved?
- What are the risks?
- What are the potential benefits?
- What side effects might occur?
- How long will the study last?
- How often do I have to come?
- How much time will it take at each visit?
- What are the chances I will receive a placebo?

Questions to consider

- Can I take my regular medications while I am in the study?
- How will my regular doctor be informed about my participation in the trial?
- How will the trial affect my everyday activities?
- What will happen if I withdraw?
- How are study results and safety of participants being checked?

Questions to consider

- Will I learn the results of the study?
- What steps are being taken to ensure my privacy?
- Where does the funding for the study come from?
- Will it cost me anything to participate?
- Will I be paid?
- What happens if I become sick or injured during the trial?

In conclusion...

- Clinical research requires complex and rigorous testing in collaboration with people and communities that are affected by the disease. As scientists & doctors seek new ways to diagnose, prevent, treat, or cure Alzheimer's disease, clinical trial participation of volunteers is essential. Current medications and more recent groundbreaking scientific advances have been possible only because of research participation of volunteers!!!

This content from:

- <https://www.nih.gov/health-information/nih-clinical-research-trials-you>
- <https://www.nia.nih.gov/alzheimers/publication/participating-alzheimers-research/introduction>
- http://www.alz.org/research/clinical_trials/clinical_trials_alzheimers.asp

Resources

- www.clinicaltrials.gov
- <http://trialmatch.alz.org>
- www.brainhealthregistry.org

Questions?

