

When Clinical Trials End

Clinical trials are research studies that closely monitor participants to test new interventions or drugs. These interventions or drugs may prevent, stop or treat disease. New Alzheimer's and dementia therapies could not happen without clinical trials, and these trials could also not happen without research participants. When a trial ends, researchers have gathered important data that help them better understand the disease. The research helps even if the results are not what we had hoped they would be. The end of a clinical research trial can cause strong emotions. The information below can help people in trials and those who care for them.

Why trials end

All clinical trials come to an end. Researchers develop a plan for a trial before it begins. This plan is called a protocol, and includes how long the study will last. If the plan goes well, a trial will end when the protocol says it will end.

Trials may also end early. That can happen for both positive and negative reasons. These reasons fall into three general groups.

- **Finding of benefit:** Scientists may find that a treatment shows good results early in the trial. If this happens, the trial may end early so they can share these findings sooner. Sometimes, participants getting an experimental treatment have results that are clearly better than the participants in the control group. The control group does not get the treatment. In this case, researchers may decide that it is unfair to continue the study.
- **Safety concerns:** Researchers may learn that an intervention is possibly unsafe. Then they will end the trial early to protect the participants.
- **Futility:** Sometimes, researchers do an analysis during a study. They look through the data collected so far. They predict outcomes of the trial. A trial may end early if an analysis shows futility. Futility means the results may turn out unfavorably and it makes sense to stop the trial.

Will participants be notified if a trial ends early?

All trial participants receive notification of important changes to their study. When a trial ends early, this process can be complicated. Trials have study sponsors. The sponsor is an organization that is in charge of the trial. An example would be a drug company.

There may be a legal requirement that the sponsor must communicate this decision quickly and publicly with its shareholders. Shareholders are people who have ownership in the company. Most of the time, this notification happens in a public press release.

Until they take this step, the study sponsor is not allowed to share this information with anyone. This includes the study sites (medical centers that are conducting the study), study teams (researchers working with participants to conduct the study) and trial participants.

This means a trial participant may learn a study ended early from news coverage or social media. This can happen before the study team is able to contact the participant.

This is not the choice of the researchers conducting the study, who understand that this information is very important to the participant. Before the trial begins, it's a good idea to talk with the study team. Ask them how updates will be shared, especially if the trial ends early.

Emotions when a trial ends

When a clinical trial ends for any reason, it is normal to feel a range of emotions. If a trial ends early because of positive results, you may feel relieved or satisfied. If a trial ends early because of unfavorable results or safety concerns, you may feel sad, disappointed, afraid, vulnerable or worried about what will happen next. These feelings are natural.

It's important to understand that all clinical studies — even those that don't lead to the desired outcome — help scientists learn more. Everything we know about current and potential Alzheimer's treatments has come from clinical trials, including those that did not meet their intended outcomes. It may be helpful to ask the study team what they learned during the trial and why it ended early. Here are some possible questions:

- Why did the trial end?
- What were the trial results?
- What are the next steps for this treatment or intervention?
- Can you share my personal results?
- Which group was I in? Did I receive the study treatment? Was I in the control group?
- Can I still receive or continue to receive the study treatment even if the trial has ended?
- Were there adverse events (side effects) during the trial? If the answer is yes, what does that mean for me personally? Did I experience side effects?

- Are there other opportunities for me to participate in a research trial?
- Where can I go for more support? Can I talk with my doctor about the trial or is the information confidential?
- Who do I contact if I have more questions?

It can also be a good idea to get information and support to help you deal with challenging feelings. Think about talking with someone you trust. That could be a family member, friend, doctor or faith leader. You can also call the Alzheimer's Association 24/7 Helpline (**800.272.3900**). See below for more ideas and resources.

Questions to ask before signing up for a clinical trial

Before you sign up for a trial, it's a good idea to ask the study team questions. This helps make sure you will understand the process and know what to expect, even if a trial ends early. Some possible questions include:

- If there's news about the trial, how will I be notified?
- Will you tell me the results of the trial? Will you tell me my personal results? If so, when?
- Will you tell me if I received the study treatment? Will you tell me if I was in the control group?
- If a trial is successful, can I keep taking the study treatment? If I was in the control group, can I start the treatment?

For more information, visit alz.org/clinicaltrials or clinicaltrials.gov. These sites may also have other questions for your clinical research team. Two more resources for help are your study guide and your study team.

TS-0122 | Updated September 2024