

“This is not just a statin study – it is a study about cognitive health.”

This is a study about preventing memory loss and dementia – something we all care about. By participating, you will help in understanding healthy brain aging for generations to come!

PREVENTABLE Participant FAQs

What is the PREVENTABLE study? PREVENTABLE is one of the largest studies in older adults. The goal is to learn if taking a statin could help older adults live well for longer by preventing dementia, disability, or heart disease.

I’ve never been involved in research. How do I know I can trust the research team?

The research team is excited to work with you. Your safety is our top concern. We are here to answer your questions along the way, and we are happy to meet with you and any support person you trust. There are rules all researchers follow to make sure that we are acting in the best interest of you and all participants. These rules include:

- Allowing you as much time as you need to make decisions about being a part of and staying in the study
- Giving written information about the study for you to review with your family members and doctors
- Having people outside the study review information along the way to make sure there are no safety concerns
- Having in place safeguards to keep your personal information secure
- Sharing updates with you during the entire length of the study

I am in my mid-nineties, and have never participated in research before. Am I too old for this study?

This is a study about function and not age. We encourage folks in their 90s to consider participating if they are a good fit for PREVENTABLE. Not everyone lives into their 90s. People who live this long are unique and resilient. We have a lot to learn from you! While some in their 90s may think about narrowing their world, others may view contributing to science as an enduring part of their legacy.

Why is diversity important to the PREVENTABLE study?

Increasing diversity in clinical research is a priority for the PREVENTABLE Study so that the results provided will be relevant and helpful to a wide range of people. Diversity helps ensure PREVENTABLE will have an impact on everyone the study intends to help.

What if I already have some memory loss? Can I still participate?

Yes! It is normal to have some memory changes as we age, particularly in our late 70s and 80s. This is normal part of aging and would not exclude you from taking part in PREVENTABLE. Even if you have “Mild Cognitive Impairment,” which is a medical term for increased memory loss associated with aging, you would still be able to participate. In fact, it is important for us to learn from people like you so that we can understand if statins may lower the risk of memory loss leading to a diagnosis of dementia. However, if you have a diagnosis of dementia from your doctor, or if you take certain medications to enhance memory (galantamine, rivastigmine, donepezil, or memantine), you are not eligible.

What if my study tests suggest potential dementia? Who will be notified?

Your health and privacy are our highest priority. This includes protecting your study-related information. If testing suggests possible dementia, we will share that information with your study doctor. You must give permission for the study doctor to share this with your primary doctor. Of note, we also keep information about your memory confidential from your trusted contacts.

Why would I join a study that lasts up to 5 years?

By joining this study, you will help us understand the potential benefit of statins in people over 75 years for outcomes that matter most (like memory and living independently). You will also receive regular follow-ups with medical professionals, including a yearly memory screening. The study lasts several years, so we have enough time to identify memory changes. However, you can decide to stop or limit your participation at any time. Joining this study is an opportunity to join a larger effort and feel a part of something bigger in order to advance medical knowledge for adults over 75 years. You would be joining 20,000 other older adults interested in helping answer this question!

April 18, 2022



PREVENTABLE

PRagmatic EVAluation of evENTs And Benefits of Lipid-lowering in oldEr adults

Can I still participate if I am planning to spend extended time outside of the U.S. for part of the year?

Yes, if you are planning to spend up to 3 months outside of the U.S., you can still participate. You can request an early refill of study drug to be mailed to your U.S. address before your travel date. The study pharmacy is not able to ship outside the U.S.

What is a statin?

A statin is a drug commonly used to lower cholesterol. Statins are frequently prescribed to patients with a history of a heart attack and stroke. Atorvastatin, also called Lipitor, is the study drug in PREVENTABLE. It is a type of statin that is well known, is proven to be safe, and has been prescribed to older adults for many years.

I am concerned about adding another medication. I'm feeling well, and I don't want to change anything.

We understand the desire to avoid more medication. This is a study drug so you only have a 50/50 chance of getting an actual statin medication. Statins have been used in many people, over many years, and they are very safe. By joining this study, you can help us learn how best to treat older adults like yourself, to help them live better for longer. You can also help us learn if statins don't make a difference for healthy older people. Please read the consent form and talk to learn if PREVENTABLE is a good fit for you.

I am more sensitive to medications in general. Is this study right for me?

You will have a 50/50 chance of being assigned to either the atorvastatin or the matching placebo (sugar pill) group if you join the study. Statins are very safe medications. If you experience any issues with the study drug, you can notify your study doctor. You and your doctor may stop the study drug for a period of time to see if your symptoms get better. If your symptoms are related to the study drug, you can stop it, but you are still part of the study. Your doctor can help answer any other questions you may have about the study drug.

I've heard that there are some side effects to taking statins like muscle aches. Should I be worried?

Statin side effects are rare. The most common side effect is muscle aches. This happens to about 5 out of every 100 people (or 5%). If you develop muscle pain after starting the study drug, you should talk to your study doctor. It can sometimes be difficult to determine if the muscle pain is caused by the study drug or due to other causes, like arthritis. Most (90%) muscle aches in older adults are actually not due to the statin itself. You can discuss options for stopping your study drug for a period of time and then resuming at a lower dose or permanently stopping your study drug with your study doctor.

Where can I learn more about statins?

There is a lot of misinformation about statins from stories in the news or conversations with family and friends. It can be difficult to find good resources with trustworthy medical information to help with your decisions about statins and your health. Talk with your doctor about finding trusted sources of information online.

My cholesterol level is normal. Why would I want to lower it?

Atorvastatin, and all statin medications, do more than just lower cholesterol. These drugs also reduce inflammation and they may help prevent memory loss, improve physical function, and even prevent cancer.

If my cholesterol level is already slightly elevated, should I take the study drug or have my doctor prescribe a statin?

The majority of individuals age 75 or older without heart disease are not taking statins. This is largely due to uncertainty about their benefit. However, starting a statin even after age 75 may help lower the risk of developing dementia. Talk with your doctor to discuss if you would be a good fit for PREVENTABLE, or if you should be on a statin at this time.

What if I have an urgent health issue or my doctor wants to know my cholesterol level?

In PREVENTABLE we do not want cholesterol levels checked, as it would reveal if a participant were taking a statin instead of the placebo. There is no health emergency that would require a current lipid level and your doctor will not need to know your level to provide you care. Lipid levels are most useful to help understand an individual's long-term health risk to prevent heart disease, but you have already lived past age 75 without heart disease. Congratulations!

I'm going to take a statin and not know my cholesterol level while I am taking part in PREVENTABLE?

Repeated lipid levels are not as valuable and do not change very much from year to year after age 65. The purpose of not drawing routine lipid levels in PREVENTABLE is to keep participants and researchers from knowing if they are on study drug or placebo. This process, called "blinding," helps prevent bias in the research results.