

“This is not just a statin study – it is a study about cognitive health”
By participating, you will leave a legacy by advancing science for healthy brain aging helping 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. This is a study about preventing memory loss and dementia – something we all care about.

What is a statin? A statin is a commonly used drug to lower cholesterol. Statins are commonly 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, with good evidence for safety, and has been prescribed to older adults for many years. 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 trial.

I am more sensitive to medications in general, would this study be right for me? 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 will stay in the study. Your doctor and the site investigator 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 such as 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. We know 90% muscle aches, a common occurrence in older adults, that are attributed to a statin 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. Other more serious side effects, such as liver injury, are even more rare. Serious side effects happen in about 1 out of every 10,000 people (or 0.0001%).

I am concerned about adding another medication. I’m feeling well and I do not want to rock the boat. We understand the desire to avoid more medication. This is a study medication so you only have a 50/50 chance of getting an actual statin medication. Statins have been used in many patients, over many years, and they are very safe. By joining this trial, 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 health elders so should not be prescribed in the first place. Please read the consent form or talk to your doctor to learn more about possible risks and benefits of joining.

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 guide your decisions about statins and your health. The Mayo Clinic and the JAMA Cardiology Patient pages online are reliable. You can find these links and other resources on our website: www.PREVENTABLEtrial.org

Why would I join a 5-year study when I don’t have to? By joining this study, you will help us understand the potential benefit of statins in people over 75 years for outcomes that matter most (memory and independence). You will also receive regular monitoring by medical professionals, including yearly memory screening. The study lasts many years as it is over the length of time needed to identify memory changes. You can give us as many years as you have to give us, we will be happy with that. This is a unique opportunity to join a larger effort and feel a part of something bigger to advance medical knowledge for adults over 75 years. You would be joining 20,000 other older adults interested in helping answer this question - science together is powerful.

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PREVENTABLE

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What if my study tests suggest probable dementia during follow up, who will be notified? Your health and privacy are our highest priority. This includes protecting your study related information. We take many steps to make sure that your data is stored securely. If testing suggests probable dementia during the study, 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.

My lipid level is normal, why would I want to lower it? Atorvastatin, and all statin medications, do more than just lower cholesterol. These drugs are also anti-inflammatory and they may help prevent memory loss, improve physical function, and even prevent cancer. However, we don't really know, which is why we are conducting the study. We do know that low cholesterol levels are very safe. Even if your cholesterol is normal, there are no negative health effects of low cholesterol.

If my lipid level is already slightly elevated, why would I take a placebo instead of getting a statin from my physician? 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 and I don't have a lipid level in my health record or my doctor wants to know it? In PREVENTABLE we do not want lipid levels checked, as it would reveal if a participant were taking a statin. There is no health emergency that would require a recent lipid level and your doctor will not need to know your lipid 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 lipid level the whole time? Repeated lipid measurements are not important in healthy older adults, and levels 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 our research results.

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 absolutely encourage folks in their 90s to consider participating if they have eligible physical and cognitive function. 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 nineties may think about narrowing their world, others may view contributing to science as an enduring part of their legacy.

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 aging and would not disqualify you from participating 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 patients like you, to understand if statins may lower the risk of progressing 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.

If I am planning to spend extended time outside of the US for part of the year, can I still participate? Yes, if you are planning to spend up to 3 months outside of the US, you can still participate. You can request an early refill of study drug to be mailed to your US address in advance of your travel date. The study pharmacy is not able to ship outside the US.

If I plan to change my permanent residence by moving out of the country in the next 5 years, can I still participate? Yes, as long as your date of move is not yet planned, as in possible but not definite, and/or if your planned move is at least two years after you first enroll. We will not be able to continue shipping study drug outside of the US once you move; however, you can request a refill prior to your move date to continue at least 3 months longer. After 3 months, you would permanently discontinue study drug use but stay in the study if you were willing to receive annual phone calls.

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