



*Help us assess the value of statins for improving outcomes meaningful to older adults.*

### About PREVENTABLE

The largest randomized trial ever conducted exclusively in older adults, PREVENTABLE tests the effectiveness of statins for the prevention of new dementia or persisting disability. The study will fill a key evidence gap regarding:

- The usefulness of statins for prolonging healthy life years and primary CV prevention in adults over age 75, especially in the setting of multiple chronic conditions.
- The usefulness of statins to address other common conditions such as mild cognitive impairment/dementia, physical disability, or heart failure with preserved ejection fraction (HFpEF) may be improved by an effective vascular prevention.

### End Points:

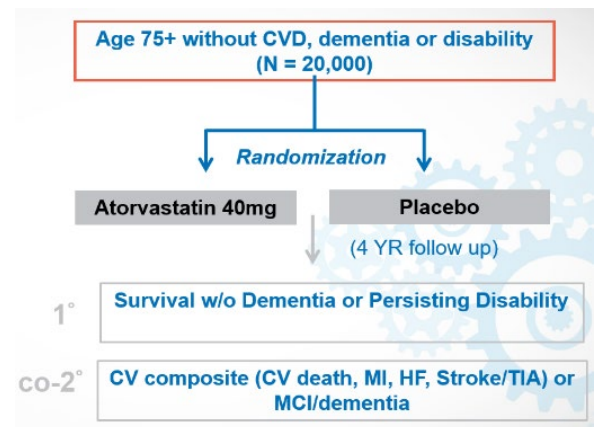
1. Survival free of new dementia or persisting disability
2. Occurrence of a cardiovascular (CV) composite of CV death, hospitalization for myocardial infarction (MI)/unstable angina, heart failure, stroke/TIA, or coronary revascularization
3. Occurrence of a cognitive composite of mild cognitive impairment (MCI) or new dementia

### Study Design

Up to 20,000 participants at 100 U.S. sites, including Veterans Administration and the Patient-Centered Clinical Research Network (PCORnet).

Participants will:

- Be randomly assigned to atorvastatin 40 mg daily or matching placebo
- Be followed through yearly phone calls for close to four years
- Receive cognitive and physical function testing at screening, over the phone, and in their home, if triggered
- Receive home delivery of study drug



### Why Atorvastatin?

- A high-intensity statin will ensure adequate therapeutic effect avoiding uncertainty about dose and outcomes
- Atorvastatin is labelled for use in this population and has demonstrated safety in pivotal trials for Lipitor approval [7% of participants aged  $\geq 75$  years (2,800/39,828)].

### How is this study pragmatic?

- Study team will query the electronic health record (EHR) to identify potentially eligible patients.
- Participants may be contacted by mail, MyChart portal message, or in-person.
- Sites have virtual/remote options for enrollment, with video/phone reviews and electronic consent
- Outcomes will be collected centrally via calls, in-home visits, and EHR data (the PCORnet Common Data Model plus Medicare).
- Participants will continue to be followed by their primary clinician.



**Who is Eligible?**

- Community dwelling adults age ≥ 75 years
- No evidence or history of MI, stroke, revascularization, or obstructive CV or peripheral vascular disease for which a statin is prescribed
- No significant disability that limits independence
- No dementia (prior diagnosis or noted by staff)
- Willing to provide Social Security number in order to facilitate linkage to Medicare and National Death Indices in this pragmatic trial
- No listed contraindication to use of a statin
- Has not taken a statin in the last 12 months

**Benefits of Participating**

**For Participants:**

- Receiving additional cognitive and physical function monitoring.
- Receiving free study drug.
- Contributing to a better understanding of how best to care for older adults.

**For Clinicians and Practice Sites:**

- Participating in a large, randomized, pragmatic non -CV primary outcome trial exclusively in older adults
- Participating in manuscripts via a publication process
- Opportunity for proposing ancillary studies via an ancillary study process

**Role of Clinicians and the Practice Site**

The study team will prescreen, consent, and enroll participants.

We may ask for your help with the following:

- Mention the PREVENTABLE study to potential participants and refer those who are interested to the study team.
- Provide potential participants with information about the study including the study team’s contact information.
- Answer questions patients and caregivers may have about PREVENTABLE.
- Contact the study team for any clinical changes that may be related to atorvastatin.

**Contact Us**

To refer a patient or if you have questions about PREVENTABLE, please contact your local study team, which can be found on the website under Study Locations. If you do not know your local study team, please email us at the address below.

Visit: [www.preventabletrial.org](http://www.preventabletrial.org)

Email: [PREVENTABLE@duke.edu](mailto:PREVENTABLE@duke.edu)

**Frequently Asked Questions (FAQs)**

**Q:** If my patient is on a statin for high cholesterol (not for secondary prevention) are they eligible for this study?

**A:** **No, patients taking a statin are not eligible.**

**Q:** What if my patient had side effects on atorvastatin, or prefers a different statin?

**A:** **A history of intolerance or side effects to atorvastatin is an exclusion criterion.**

**Q:** How will I know if my patient is enrolled in PREVENTABLE?

**A:** **Enrollment information will be available in the EHR.**

**Q:** Will I be able to see the study drug prescription in the EHR?

**A:** **Yes, in a research tab or medication list in the EHR**

**Q:** Should I order lipid panels on my patients who are participating in this study?

**A:** **No, ordering lipid panels will likely result in unblinding of participants and is strongly discouraged.**

**Q:** Will clinicians know about the results of the cognitive testing?

**A:** **Yes, if a study participant is adjudicated as having probable dementia, the study team will inform the clinician if the participant consented to this at study entry.**