# Do Statins Prevent Dementia in Healthy Older Adults? STAREE Trial Weighs In

Written by The Life Science Feed Editorial Team · Published 23 July 2026 · Edited by William Lopes

For decades, clinicians have debated the role of statins in primary prevention, particularly in older adults without established cardiovascular disease. The question of whether these lipid-lowering agents offer benefits beyond heart attack and stroke prevention, specifically in cognitive health, has remained a persistent clinical dilemma. The STAREE trial aimed to provide clarity on these complex issues, focusing on a population often excluded or underrepresented in major cardiovascular outcomes trials.
This large-scale, randomised, placebo-controlled study specifically investigated if statin therapy could reduce the risk of major cardiovascular events or dementia in healthy individuals aged 70 and older. The results offer a nuanced picture, confirming some expected benefits while definitively ruling out others in this specific demographic.

**KEY TAKEAWAYS**

- The Pivot: The STAREE trial definitively showed no benefit of statin therapy in preventing dementia or cognitive decline in healthy adults over 70.
- The Data: Statin therapy reduced the risk of major cardiovascular events by 20% (HR 0.80; 95% CI, 0.67-0.96; P=.016) in this population.
- The Action: Clinicians should continue to weigh cardiovascular benefits against potential harms and patient preferences when considering statins for primary prevention in healthy older adults, but should not prescribe them for dementia prevention.

The global burden of cardiovascular disease and dementia continues to rise, particularly in ageing populations. While statins have unequivocally demonstrated efficacy in secondary prevention and high-risk primary prevention, their role in healthy older adults without overt cardiovascular disease or high cholesterol has been less clear. Clinicians have long grappled with balancing the potential for cardiovascular protection against the risks of polypharmacy and adverse events in a frail, elderly cohort. The prospect of statins offering a 'two-for-one' benefit, by also preventing cognitive decline, has been a tantalising but unproven hypothesis, driving much of the interest in trials like STAREE.
The STAREE (Statins in Reducing Events in the Elderly) trial enrolled 18,000 participants aged 70 years or older from Australia and the United States. All participants were free of known cardiovascular disease, dementia, or physical disability at baseline. Investigators randomised individuals 1:1 to receive either atorvastatin 40 mg daily or placebo. The primary outcomes were major cardiovascular events (a composite of non-fatal myocardial infarction, fatal coronary heart disease, non-fatal stroke, fatal stroke, or coronary revascularisation) and dementia. Secondary outcomes included

all-cause mortality, incident frailty, and persistent physical disability. The trial followed participants for an average of 4.4 years. Investigators at Monash University led the extensive multinational effort.1

## What the trial actually measured

STAREE was designed to address two distinct, but equally pressing, clinical questions: could statins prevent cardiovascular events in a healthy, elderly population, and could they also stave off cognitive decline? The trial's dual primary endpoints reflected this ambition. Participants underwent comprehensive cognitive assessments at baseline and annually thereafter, including the Montreal Cognitive Assessment (MoCA) and a battery of neuropsychological tests. These measures aimed to detect subtle changes in cognitive function that might precede a formal dementia diagnosis. Cardiovascular events were adjudicated by an independent committee, ensuring rigorous and unbiased assessment of the primary cardiovascular endpoint. The study's large sample size provided substantial statistical power to detect clinically meaningful differences in both outcomes, assuming such differences existed.1

The trial's inclusion criteria specifically targeted healthy older adults, meaning individuals with a history of myocardial infarction, stroke, or transient ischaemic attack were excluded. Participants also could not have a baseline diagnosis of dementia or a Mini-Mental State Examination (MMSE) score below 24. This careful selection aimed to isolate the effect of statins in true primary prevention, avoiding confounding from pre-existing conditions that might independently influence cardiovascular or cognitive outcomes. The median age of participants was 74 years, with 51% being female. Baseline lipid profiles showed a mean LDL-C of 3.2 mmol/L, indicating a population that, while healthy, was not necessarily at exceptionally low cardiovascular risk.1

## The numbers

Statin therapy did not reduce the incidence of dementia. Over the median follow-up of 4.4 years, 3.7% of participants in the atorvastatin group developed dementia, compared to 3.8% in the placebo group. This translated to a hazard ratio of 0.98 (95% CI, 0.86-1.12; P=.79), a clear non-significant finding. No difference emerged in any of the secondary cognitive endpoints, including mild cognitive impairment or changes in specific cognitive domain scores. This result definitively closes the door on the hypothesis that statins offer a primary preventive benefit against dementia in this population.1

But statins did reduce major cardiovascular events. The atorvastatin group experienced a 20% reduction in the composite primary cardiovascular endpoint (HR 0.80; 95% CI, 0.67-0.96; P=.016). This translates to an absolute risk reduction of 0.9 percentage points over the follow-up period, meaning 111 healthy older adults would need to be treated with atorvastatin for 4.4 years to prevent one major cardiovascular event (NNT 111). This benefit was driven primarily by reductions in coronary revascularisation (HR 0.70; 95% CI, 0.55-0.89; P=.004) and non-fatal myocardial infarction (HR 0.70; 95% CI, 0.51-0.97; P=.03). No significant difference appeared in stroke rates (HR 0.92; 95% CI, 0.69-1.23; P=.58) or cardiovascular mortality (HR 0.93; 95% CI, 0.69-1.26; P=.66).1

All-cause mortality also showed no significant difference between the groups, with 5.9% in the atorvastatin group dying compared to 6.1% in the placebo group (HR 0.96; 95% CI, 0.84-1.10; P=.59). This lack of mortality benefit, despite the reduction in cardiovascular events, is a common observation in primary prevention trials with relatively short follow-up periods in older populations. The trial also examined incident frailty and persistent physical disability, finding no significant differences in either outcome. This suggests that while statins offer some cardiovascular protection, they do not broadly improve overall health or functional status in this healthy older cohort.1

## Safety and tolerability

The safety profile of atorvastatin in STAREE was consistent with previous trials, though with some expected differences in an older population. Muscle-related adverse events, including myalgia and muscle weakness, were reported by 5.2% of participants in the atorvastatin group compared to 4.3% in the placebo group (P=.04). While statistically significant, this difference was modest and did not lead to a higher rate of treatment discontinuation due to muscle symptoms. New-onset diabetes occurred in 3.1% of the atorvastatin group versus 2.6% in the placebo group (P=.06), a trend that did not reach statistical significance but aligns with known class effects of statins.1

Serious adverse events were similar between the groups, with 27.8% in the atorvastatin group and 27.1% in the placebo group experiencing at least one serious event. No unexpected safety signals emerged. The incidence of cataracts, a concern sometimes raised with statin use, was also similar between the groups. Overall, atorvastatin 40 mg daily was well-tolerated, but the modest increase in muscle symptoms and the trend towards new-onset diabetes highlight the need for careful patient selection and monitoring in this age group. Clinicians should consider these potential side effects when discussing the benefits and risks with their older patients.1

## Where it falls short

The STAREE trial, while robust, has limitations. The median follow-up of 4.4 years, while substantial for a primary prevention trial, might be insufficient to observe a significant impact on all-cause mortality or the full spectrum of dementia progression. Dementia is a slow, insidious process, and longer follow-up periods, perhaps 10 years or more, might be necessary to definitively rule out any long-term cognitive benefits or harms. The trial also focused on a relatively healthy older population; whether these findings extend to older adults with more comorbidities or those approaching frailty remains an open question. The Oxford Handbook of General Practice offers a concise guide for managing complex patients, but even that cannot fully address the nuances of individual patient risk in this demographic.

Another consideration is the specific statin and dose used. Atorvastatin 40 mg is a moderate-to-high intensity statin. While this dose is effective for lipid lowering, it is possible that a lower dose might have yielded a similar cardiovascular benefit with fewer side effects, or that a different statin might have performed differently. The generalisability of these findings to other statins or different dosing strategies is not directly addressed by STAREE. Furthermore, the trial did not stratify participants by baseline cardiovascular risk scores, which could have provided more granular insights into which subgroups might derive the most benefit from statin therapy. The lack of a clear mortality benefit also tempers enthusiasm for widespread statin use in this population, reinforcing the need for individualised risk-benefit assessments.1

The trial's primary outcome for dementia was incident dementia, diagnosed using established criteria. However, the study did not explore the potential for statins to influence specific subtypes of dementia, such as vascular dementia, which might theoretically be more responsive to lipid-lowering therapy. While the overall finding for dementia prevention was negative, a more granular analysis of dementia subtypes could offer additional insights, though this would likely require a much larger and longer trial. The trial also did not include a robust assessment of quality of life, which is a critical consideration for older adults weighing preventive therapies.1

“We have a clear answer on dementia: statins do not prevent it in healthy older adults. But the cardiovascular benefit, while modest, is real. It forces a careful conversation with patients.”

Sarah Gellar, Clinical Trials EditorThe STAREE trial provides important evidence for clinicians considering statin therapy in healthy adults over 70. It confirms a modest cardiovascular benefit, consistent with the broader statin literature,

but unequivocally demonstrates no role for statins in preventing dementia or cognitive decline in this population. This clarity is valuable for guiding shared decision-making, allowing clinicians to focus discussions on the proven cardiovascular benefits and the associated risks, rather than speculative cognitive advantages. The NNT of 111 for cardiovascular events underscores that while the benefit is statistically significant, the absolute benefit for any individual patient is small, necessitating a careful consideration of patient preferences, comorbidities, and potential adverse effects.1

### CLINICAL IMPLICATIONS

The STAREE trial delivers a clear message: do not prescribe statins to healthy older adults solely for dementia prevention. This finding should simplify clinical conversations, allowing us to pivot away from an unproven hypothesis. Clinicians can now confidently state that statins do not offer a cognitive shield in this population, which is a significant piece of evidence for shared decision-making.

But the cardiovascular benefit, while modest, remains. A 20% reduction in major cardiovascular events, even with an NNT of 111 over 4.4 years, is not insignificant for a primary prevention strategy. We must continue to weigh this against the potential for muscle symptoms and the slight increase in new-onset diabetes, particularly in a population where polypharmacy and frailty are common concerns. The Oxford Handbook of Cardiology provides an excellent framework for these complex risk assessments.

The lack of an all-cause mortality benefit is also a critical point. For many healthy older adults, extending life is less of a priority than maintaining quality of life and functional independence. Preventing a non-fatal myocardial infarction is valuable, but if it comes with daily muscle aches and no overall survival advantage, the calculus changes for some patients. We need to be transparent about these trade-offs.

Ultimately, STAREE reinforces the principle of individualised care. It is not a blanket endorsement or rejection of statins for healthy older adults. Instead, it provides the precise data needed to have an honest, evidence-based discussion with patients about what statins can and cannot do for them, allowing them to make informed choices about their health in later life.

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### REFERENCES

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