

ASPREE Participant FAQs

Question 1: When do I stop taking study medication?

You should stop taking the study pills when you receive this letter.

Question 2: What do I do with the leftover study tablets?

Please write the date you stopped taking the tablets on the Health Event Report Form, place the bottle and form in the enclosed reply paid envelope and mail them back to us.

Question 3: What do I do if I have already stopped taking study medication on the advice of my doctor?

You should follow health advice from your doctor. If you still have your bottle of study medication, please write the date when you stopped taking the tablets on the Health Event Report Form, place the bottle in the enclosed reply paid envelope and mail it back to us.

Question 4: What do I do if my doctor has prescribed aspirin?

You should continue taking aspirin if it has been prescribed by your doctor.

Question 5: How does the decision to stop taking study medication affect my participation in ASPREE?

Your participation in ASPREE does not change, other than not taking study medication. Please continue to attend study visits and take phone calls for the remainder of 2017. Your continued participation will help provide information on delayed effects of low-dose aspirin.

Question 6: Why is the study continuing since you have already found it is unlikely to extend life free of physical disability or dementia?

There is still much more to learn about low-dose aspirin in older people, for example the effect on specific diseases as people age. Even though you won't be taking any study medication, your ongoing participation will help us gather important health information. Continuing until the end of 2017 also gives time for all participants to complete their planned ASPREE study visits.

Question 7: Should I come for my Milestone visit?

Yes, please. ASPREE is continuing – there just won't be any study medication to take.

Question 8: Why do I have to complete the enclosed Health Event Report Form?

The information we are collecting is very important to have a better understanding about the effects of low-dose aspirin in older people. The questions are the same as we have asked during your previous phone or study visits. Please mail the completed form back to us along with any unused study medication in the enclosed pre- paid envelope.

Question 9: Who do I call to ask more about ASPREE?

Contact your study site. The contact details are on the letter.

Question 10: When will I find out what study medication I was on – aspirin or placebo?

We will obtain the best quality and reliable data about aspirin if participants and Study Investigator's do not know who was taking aspirin or placebo (inactive pill) until the results are published. If you want to know if you have been taking aspirin or placebo, we can notify you once we have published the main results of the study.

Question 11: When will the main results be published?

We expect the results to be published in early 2018.

Question 12: Who made the decision that I should stop taking the study tablets sooner than planned?

The US National Institute on Aging (NIA) is a government research agency that provided most of the funding for ASPREE. For the past seven years it has been carefully monitoring the progress of ASPREE.

Question 13: Why was the decision made?

On reviewing the most recent data, NIA has not seen a statistically significant difference in participants' survival free of dementia and disability between those taking aspirin and those taking placebo. The NIA has now concluded that it is extremely unlikely that the study would show a benefit for this primary outcome even if participants continued to take study medication through December 2017 as originally planned.

Accordingly, NIA decided that the treatment with study medication should stop.

Question 14: Does ASPREE have study results, beyond what you already told me?

Not yet. We are still collecting data and are unable to answer additional questions until we collect and analyze all the data.

Question 15: When will the study results be available?

ASPREE has generated a large amount of health information that grows daily. We will still be collecting data for the ASPREE study until the end of 2017. It will take several months to analyze and prepare for publication. We hope to have this completed by early 2018.

Question 16: What is next for the ASPREE study?

First, we must complete the 2017 visits in all the ASPREE participants and collect all the study medication. Second, statisticians will analyze the huge amount of information collected over the 7 years of visits and phone calls to answer the questions about low-dose aspirin's risks and benefits.

But our work is not done. We hope to continue following everyone who was part of the ASPREE study for a longer term follow up study, called ASPREE-XT. This will allow us to learn more about the long-term effects of aspirin as we age. Therefore, we will be seeking your willingness to continue.

We will provide more information about ASPREE-XT as soon as we can.

Question 17: Will ASPREE-XT involve in-person visits?

Yes, we hope so.

Question 18: Will my doctor be notified about which study medication I was on?

Now that you will no longer be taking study medication, it is unlikely that your Health Care Provider will require this information for your routine care.

However, the ASPREE study has a procedure in place to provide this information at your doctor's request if she/he believes it is important for your care.

Question 19: Does the decision to stop the treatment phase mean that I should never take aspirin?

As always, any health decision including whether to take aspirin, should be made in consultation with your physician (GP).

Question 20: Will the ACES Sub-Study blood collection and tumor tissue collection (for those who develop cancer) continue?

Yes, we will continue to collect bloods for the biorepository as planned through 2017. Tumor tissue will also continue to be collected when available.