ASPREE XT
ASPirin in Reducing Events in the Elderly- eXTension
ASPirin in Reducing Events in the Elderly
ASPREE

About a TABLET

SUMMER-AUTUMN 2019

World's largest aspirin study in healthy older people releases key results

ASPREE puts ageing centre stage

Above: ASPREE & ASPREE-XT Principal Investigator in Australia, Prof. John McNeil said results from ASPREE will change how doctors practice medicine.

Release of the main ASPREE results in September 2018 sparked a storm of global interest in aspirin and older people.

Such was the importance of ASPREE to doctors and the older community that large international media outlets - ***The New York Times, Washington Post, CNN, NBC (US), CBC (Canada) and the BBC (UK) -*** *reported on the findings.*

ASPREE showed that daily low dose aspirin did not extend years of good health (free from physical disability or dementia) in healthy older people (those without a medical reason to take the drug).

The results were published in the New England Journal of Medicine.

National and international scientists, medical professionals, journalists, health writers and the public took to all forms of media (print, TV, radio and online) to share and/or comment on the new discovery.

ASPREE findings were relayed across continents and in at least 47 countries around the world.

Overall, there were more than 16,000 known media mentions of ASPREE. Approximately 24 million people were exposed to some type of story about the results of your study!

Aspirin is one of the most popular preventive drugs in the world - millions of healthy older people, without a medical reason, take daily aspirin believing it is good for them.

ASPREE, for the first time, provided *strong scientific evidence* to rethink this practice.

Older people unsure whether they should take daily low dose aspirin, should speak to their doctor for individual advice. (This applies to our participants too.)

Very little medical research is conducted in older people, even though as we age we are more likely to develop disease and have a greater need for medication. Without the generosity and commitment from you, our study participants, and the support from more than 2000 GPs, the ASPREE study would not have been possible and the world would not have this new important knowledge.

But this is only the beginning; we look forward to sharing many more ASPREE findings.

Your efforts to improve healthy ageing in older people are already making their mark around the world. We hope you will continue to participate in this medical research in the follow up ASPREE-XT study.

Links to national and international ASPREE articles can be found in the 'news' section of our website, aspree.org

Above: The New York Times Health section announces ASPREE study findings to its 1.17 million followers on Twitter.

RESEARCH TALK

If you are interested in science and health and want to know more about research, this column is for you.

What do you mean by a 'paper' being published in a journal?

A 'paper' or an 'article' is a record of a study's purpose, the data (information), how the data were analysed and the results or findings from that analysis. Study investigators write and submit the 'paper' to a medical journal. ASPREE had three major papers published in the New England Journal of Medicine in September 2018. An example of an extract or summary of one of these is on the right.

Why does it matter which journal publishes the research papers?

Prestigious journals, such as the New England Journal of Medicine, only accept research of the highest quality and importance; the rest they reject. Prestigious journals are known for their very thorough peer-review process, which involves close scrutiny of every piece of information in each paper before publication.

Why is the peer-review process important?

During the peer-review process, independent, journal-appointed academics with relevant clinical expertise, check the accuracy and quality of information in the paper. This can be a very time-consuming process, but it is a necessary check of the research's rigour.

What do you mean by 'disability-free' survival?

For the purpose of the ASPREE study, 'disability-free survival' means being alive after an average 4.7 years without dementia or a persistent physical disability. In other words, the study determined whether low dose aspirin extended the time an older person functioned independently (e.g. able to shower or dress without help).

ABSTRACT

Effect of Aspirin on Disability-free Survival in the Healthy Elderly

BACKGROUND
Information on the use of aspirin to increase healthy independent life span in older persons is limited. Whether 5 years of daily low-dose aspirin therapy would extend disability-free life in healthy seniors is unclear.

METHODS
From 2010 through 2014, we enrolled community-dwelling persons in Australia and the United States who were 70 years of age or older (or ≥65 years of age among blacks and Hispanics in the United States) and did not have cardiovascular disease, dementia, or physical disability. Participants were randomly assigned to receive 100 mg per day of enteric-coated aspirin or placebo orally. The primary end point was a composite of death, dementia, or persistent physical disability. Secondary end points reported in this article included the individual components of the primary end point and major hemorrhage.

RESULTS
A total of 19,114 persons with a median age of 74 years were enrolled, of whom 9525 were randomly assigned to receive aspirin and 9589 to receive placebo. A total of 56.4% of the participants were women, 8.7% were nonwhite, and 11.0% reported previous regular aspirin use. The trial was terminated at a median of 4.7 years of follow-up after a determination was made that there would be no benefit with continued aspirin use with regard to the primary end point. The rate of the composite of death, dementia, or persistent physical disability was 21.5 events per 1000 person-years in the aspirin group and 21.2 per 1000 person-years in the placebo group (hazard ratio, 1.01; 95% confidence interval [CI], 0.92 to 1.11; P=0.79). The rate of adherence to the assigned intervention was 62.1% in the aspirin group and 64.1% in the placebo group in the final year of trial participation. Differences between the aspirin group and the placebo group were not substantial with regard to the secondary individual end points of death from any cause (12.7 events per 1000 person-years in the aspirin group and 11.1 events per 1000 person-years in the placebo group), dementia, or persistent physical disability. The rate of major hemorrhage was higher in the aspirin group than in the placebo group (3.8% vs. 2.8%; hazard ratio, 1.38; 95% CI, 1.18 to 1.62; P<0.001).

CONCLUSIONS
Aspirin use in healthy elderly persons did not prolong disability-free survival over a period of 5 years but led to a higher rate of major hemorrhage than placebo. (Funded by the National Institute on Aging and others; ASPREE ClinicalTrials.gov number, NCT01038583.)
https://www.nejm.org/doi/full/10.1056/NEJMoa1800722

Above: The 'abstract' or summary of the main ASPREE study paper published on the New England Journal of Medicine website. All three ASPREE papers should be available to view in their entirety, for free mid 2019.

Below: Example of one of the major medical community responses to ASPREE findings.

Harvard Health Publishing
HARVARD MEDICAL SCHOOL
Trusted advice for a healthier life

Deepak Bhatt, MD, MPH
Editor in Chief, *Harvard Heart*

"Three articles pertaining to this trial were published in the prestigious *New England Journal of Medicine*, which is an unusual degree of coverage for one trial and highlights its immediate relevance to clinical practice."
https://www.health.harvard.edu/blog/aspirin-for-primary-prevention-of-cardiovascular-disease-part-2-2018092514890

Another world-first: ASPREE-XT

An unprecedented opportunity to further address the lack of research in older people is underway! And it builds on Prof. John McNeil's vision of a large, engaged group of older Australians leading the charge.

But we need you, our participants, for the ASPREE-XT study to become the flagship research project that aims to improve health for future generations of older people.

Your participation in ASPREE-XT will add to medical knowledge about health and ageing (regardless of which study tablet you may have taken in ASPREE, or for how long).

While ASPREE will tell us about the effect of aspirin on health during the trial, there is much more to be learned. For example, **the longer term effect of aspirin on cancer has never been studied solely in older people,** despite older people being at higher risk of getting cancer. Cancer develops over time and the effect of aspirin on cancer prevention may not have been evident during the ASPREE study.

Another question is the longer term effect of aspirin on dementia, or why some people over the age of 70 become frail and unwell while others do not?

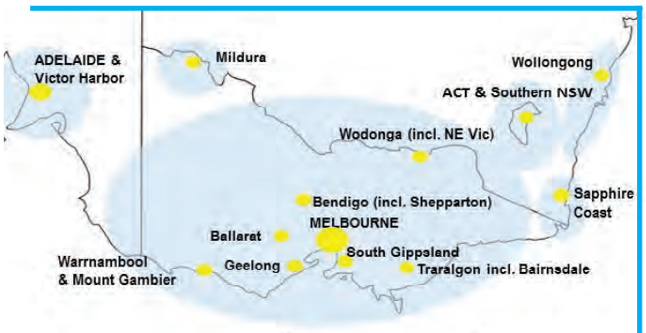
By participating in ASPREE-XT, you will help answer these questions and help identify factors that may contribute to older onset diseases or indeed, a long, healthy life.

Life-expectancy has increased globally; your participation in ASPREE-XT will contribute to high quality research to help maintain good health during this increased lifespan.

There are no study tablets to take in ASPREE-XT. Involvement includes free annual health checks conducted at the same locations as ASPREE (see maps).

We can work around your personal circumstances. If it's not easy to attend a visit, let our team know if you need assistance.

If you need a copy of, or help with, the ASPREE-XT consent form, please call our team on 1800 728 745 (toll free from a landline).



Australian & US study sites

ASPREE KEY FACTS

Total: 19,114 participants

(16,703 AUS, 2,411 in US)

- Female participants: 10,783
- Male participants: 8,331
- Av. age at start of trial: 74 yrs
- A community based study, co-ordinated through 16 sites in south eastern Australia and 34 sites in the US.
- The largest trial to weigh benefit of aspirin vs risks in healthy people aged ≥ 70 yrs (≥ 65 yrs Hispanic and African Americans).
- Primarily undertaken through general practice in Australia, and supported by >2000 GP associate study investigators.
- Funded by the US & Australian Governments.
- A double-blind, randomised placebo controlled trial of 100 mg enteric coated aspirin vs placebo for an average 4.7 yrs.
- 9525 participants assigned aspirin; 9589 matched placebo
- All participants were free of dementia, known cardiovascular disease & significant physical disability at enrolment into trial.
- ASPREE started March 2010
- Study tablets ceased June 2017
- ASPREE formally concluded in January 2018
- Three ASPREE papers published in the New England Journal of Medicine in September 2018:

1. Effect of Aspirin on Disability-free Survival in the Healthy Elderly
2. Effect of Aspirin on All-Cause Mortality in the Healthy Elderly
3. Effect of Aspirin on Cardiovascular Events and Bleeding in the Healthy Elderly

- A need to understand longer term effects of aspirin led to a new, follow-up study which will identify how aspirin and other factors impact health in older people. This study, called ASPREE-XT, commenced February 2018.

About a TABLET

SUMMER - AUTUMN 2019

Latest ASPREE paper

Image: Unsplash

Title: Quality of Life for 19,114 participants in the ASPREE (ASPirin in Reducing Events in the Elderly) study and their association with sociodemographic and modifiable lifestyle risk factors.

Authors: ASPREE Investigators in Australia and the US, led by Prof. Nigel Stocks, GP and Chief Investigator of ASPREE in South Australia.

Journal: Quality of Life Research, published online 8th November 2018

In a nutshell: This paper essentially looks at the roles that age, gender, place of dwelling, education, smoking or drinking have on physical and mental wellbeing of ASPREE participants in Australia and the US.

An analysis of relevant data collected at enrolment showed that, overall, ASPREE participants had a better quality of life than those in other studies in this age-group, most likely due to their good health. Males, younger ASPREE participants, those with more education or activity levels and those who drank 1 - 2 alcoholic drinks a day reported a higher quality of life, particularly for physical wellbeing. Current heavy smokers had the lowest physical wellbeing. Mental wellbeing was slightly higher in Australian men living at home with family and friends and residents living in outer/remote Australia.

Note: These findings do not apply to the wider population and exclude other factors affecting health and wellbeing such as diet and conditions such as arthritis. However this paper does give an important starting point on which to identify issues affecting quality of life in ASPREE participants as they age.

Published ASPREE papers are under the 'researchers' tab on www.aspree.org

CALL OUT FOR PARTICIPANT INPUT ON ASPREE AND ASPREE-XT COMMUNICATIONS

We strive to keep you well informed of the progress and findings of ASPREE and ASPREE-XT (and sub-studies) through letters, newsletters, our website and at study updates.

As the volume of findings from the ASPREE study increase, it would be very helpful to know what you would like to most hear about and how. If you have the spare time and the inclination to provide feedback on communications, please email an expression of interest to: aspree@monash.edu or ring our team on 1800 728 745 (toll free from a landline).

Your feedback may be sought through brief online questionnaires or discussions online, via phone or in person. Your input on communications about the studies can be as much or as little as you wish and you can stop at any time.

Staying in touch with you is very important

- Have you moved?
- Do you have feedback? We love to hear positive and constructive feedback.
- Have a question about ASPREE or ASPREE-XT?
- Rather receive 'About a Tablet' newsletter by email?

CALL:
1800 728 745
(toll free from a landline)

Email: aspree@monash.edu
Website: www.aspree.org
@aspree_aus

Newsletter produced by ASPREE National Co-ordinating Centre, Melbourne

ASPREE-Anaemia searches the unknown

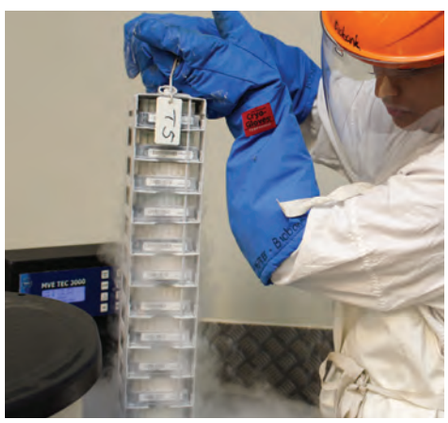
The latest ASPREE sub-study, ASPREE-Anaemia, aims to understand why some well older people become anaemic while others do not. Anaemia is the term for low levels of haemoglobin, a protein in the blood which carries oxygen around the body.

In approximately 30% of cases of anaemia in older people, the cause is unknown.

All participants had normal levels of haemoglobin when they enrolled in ASPREE. ASPREE-Anaemia will investigate how frequently healthy older people develop anaemia, the causes and its effect on quality of life. It will also determine the effect of aspirin on anaemia in older people.

Researchers will measure and compare a range of biomarkers (such as certain proteins, vitamins, hormones and indicators of inflammation) in participants' blood samples stored in the Healthy Ageing Biobank.

More information about all sub-studies can be found on www.aspree.org



Above: Blood samples in the ASPREE Healthy Ageing Biobank will be used to help researchers understand what causes anaemia in some well older people and not others.

ASPREE-XT Funding Organisations

- National Institute on Aging (NIA/NIH in the US)
- National Health and Medical Research Council of Australia (NHMRC)
- National Cancer Institute (NCI/NIH in the US)
- Monash University

ASPREE-XT Collaborating Organisations

- Monash University
- Menzies Institute for Medical Research, University of Tasmania
- Australian National University
- The University of Adelaide
- Berman Center for Outcomes & Clinical Research (Minnesota, US)