

THE TABLET

SUMMER EDITION 2015/2016

ASPREE (ASpirin in Reducing Events in the Elderly) is:

- A community based study, primarily undertaken in general practice
- Funded by the US & Australian Governments
- A double-blind, randomised, placebo-controlled trial
- Will determine whether low-dose aspirin can help older people stay healthier for longer

The world's largest disease prevention aspirin study in healthy people aged 70 plus

Participants in Australia's largest clinical trial: **16,703** (2,411 USA)

- Females: 9,175
- Males: 7,528

Age of Australian ASPREE participants: (As of Dec 2015)

Average: 78 years **Oldest:** 98 years

ASPREE locations: Victoria, Tasmania, Adelaide, Mount Gambier, ACT and Southern NSW, Sapphire Coast and Wollongong

WHY STUDY ASPIRIN IN HEALTHY OLDER PEOPLE?

- Knowledge of whether healthy older people should take low-dose aspirin will only come from a study that considers all the potential benefits and risks in that age group.
- No previous clinical trial of aspirin has before focussed on healthy older people.
- People are living longer. If life expectancy increases at the same rate observed in recent history, 50% of Australian babies born today are predicted to live to 104.
- ASPREE is investigating the common causes of disability in older people such as dementia, cancers and cardiovascular disease (heart attack and stroke).
- At the heart of the ASPREE study is a goal to discover how to maintain good quality of life within an increased lifespan.

NEW ASPREE WEBSITE

Have you visited the new ASPREE website yet?

Stay up to date on ASPREE happenings and events on www.aspree.org

Web preview on page 3.

Your Health Information



All ASPREE participants gave their permission to share health information from Medicare and the Pharmaceutical Benefits Scheme (PBS) when they first enrolled in the study.

As Australians experiencing life over the age of 70, sharing this health information with ASPREE researchers is very much appreciated. We are able to learn about age-related issues, such as access to medical care and medicines, from those experiencing it first-hand.

Although you did provide your consent, the Department of Human Services (DHS) requires you to complete and sign the additional consent form enclosed with this newsletter, before they will release

your health information to the ASPREE study.

Medicare records provide a summary of the number of medical visits, the length of the consultation, e.g. a level B consultation, and the item number for claimable investigations such as an ECG.

With this information, ASPREE researchers will be in a position to analyse how access to health services may vary according to location, age, gender and well-being. Do healthier older Australians see a doctor more or less often than the national average? We really won't know until we have the data.

Medicare records **do not** give the reason for the consultation or the results of investigations.

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Your Health Information

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PBS reports list all prescribed medications subsidised by the government. This helpful summary provides a picture of medications taken by older Australians in various stages of health.

PBS records will also let us know about medications prescribed throughout the year, such as antibiotics, that may be otherwise missed at an annual study visit.

Principal Investigator of the ASPREE study in Australia, Professor John McNeil said that while there is no obligation, he encourages all participants to consider completing the DHS consent form.

"ASPREE is investigating the most common causes of disability in older people, such as dementia, depression, cancers and cardiovascular disease. Medicare and the PBS records will be of enormous value to help understand other factors that may affect ageing," said Prof McNeil.

Even if you have had to stop taking ASPREE study medication for medical reasons, PBS and Medicare summaries are important and will tell us about ageing with and without aspirin.

Once we receive the completed form in the enclosed reply paid envelope, there is nothing more you need do to ensure we have this health information.

All participant information collected during the trial, including Medicare and the PBS data, is de-identified (allocated an ID number) and entered into a secure database. As always, no individual is identified in study findings.

Returning the DHS consent form is entirely voluntary, and whether or not you choose to mail it back will not in any way impact your involvement in the main ASPREE study.

We would also like to thank the 250 ASPREE participants who completed these consent forms late last year. The high response rate affirmed the decision to post the forms to all participants.

For questions about the DHS consent form feel free to contact an ASPREE team member on 1800 728 745.

Researchers have long believed that our genes play a role in the type of diseases we may or may not develop later in life.

Thanks to participants in the Healthy Ageing Biobank, researchers now have a high quality resource to better understand the impact of genes on health in older people.

Health & Ageing: Hunt for Genetic Link

What is genetic research?

Genes are the 'blue-print' of a person's characteristics and traits. Genes determine physical traits such as the colour of our eyes and hair. They also contribute, in combination with the environment, to more complex traits such as our personality, human behaviour and risk of certain diseases.

Every person inherits one set of genes from each parent, creating a wonderfully unique set of genetic blue-prints that makes you, you. The complete set of your genetic information is known as a genome.

ASPREE is collaborating with specialist genetic researchers to read genomes in the Healthy Ageing Biobank. The process of reading genetic information on genomes is called genomic sequencing, and it will help discover ways to improve health outcomes for older people globally.

To give you an idea of the amount of genetic information in our genomes, imagine having two 20,000 page books (one from each of your parents) where every page represents an individual gene. Genome sequencing reads *every letter on every page*.

In some studies, researchers may be seeking to identify a genetic change equivalent to finding one changed letter in a 20,000 page book!

What will this tell us?

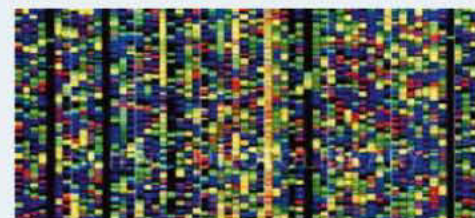
Almost every disease has a genetic component. It stands that good health also has a genetic component.

While genomic sequencing will reveal an enormous amount of genetic information,

the sequences have no meaning without extensive analysis and interpretation. That's the mammoth challenge faced by genetic researchers. First they need to identify which genes affect health. Then they need to understand how these genes behave and interact with other genes, and how they are affected by environmental factors, such as diet. This is a highly specialised field of research.

National and international collaborative researchers will have the leading technologies and expertise to provide high quality analysis and interpretation of genetic information. All samples read and analysed by collaborators are de-identified, meaning that the donor's identity is never disclosed. No individuals can be identified in reports.

Given the complexity of human genomes, it will be some years before findings are available.



Above: computer representation of genetic information on a genome.

When will genetic research start?

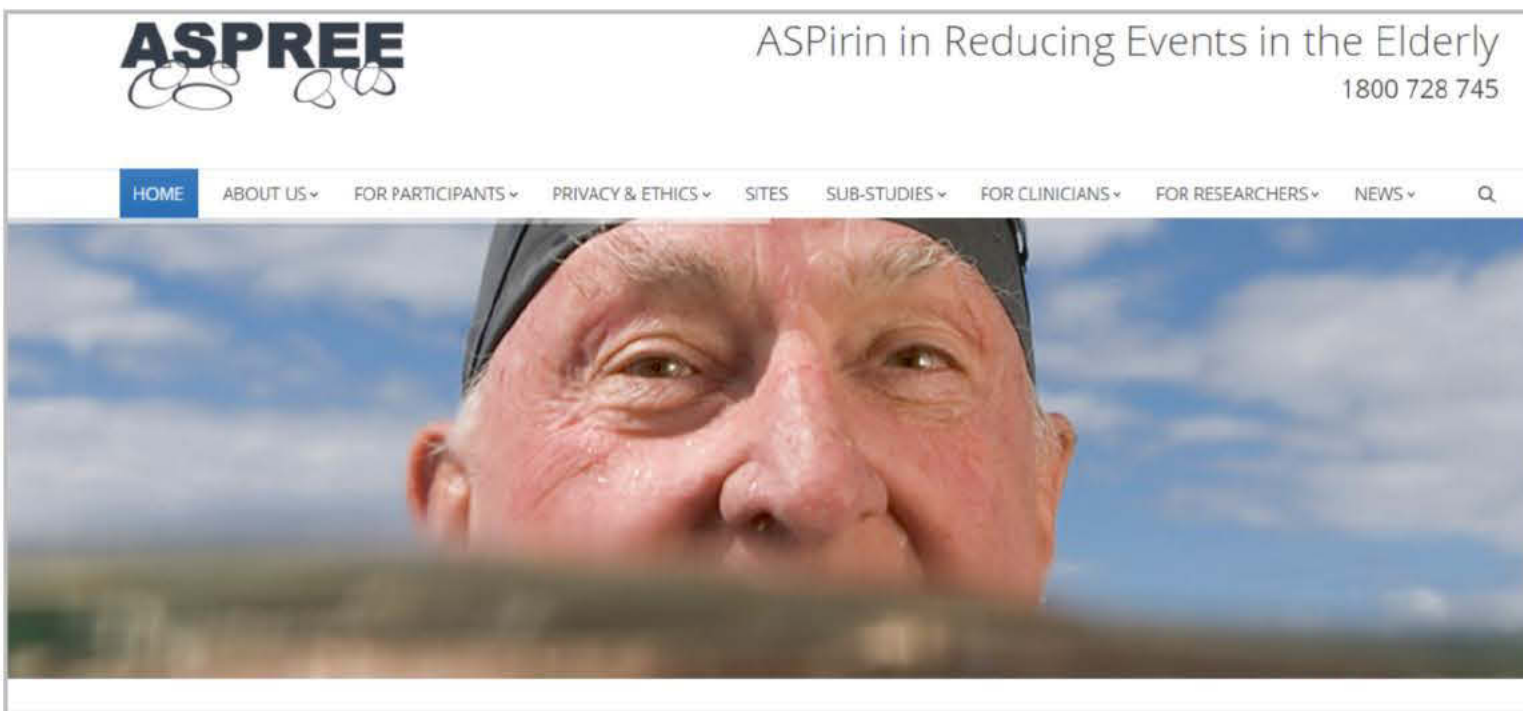
ASPREE and the Sax Institute '45 and Up' Study in NSW are collaborating with The Garvan Institute of Medical Research in Sydney to develop a Medical Genome Reference Bank.

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One-stop-site for study information

A major overhaul of the ASPREE website has made it easier than ever before to stay up to date on study-related activities and news! Visit us at www.aspree.org

With an increasing number of older people accessing the internet, we've created a new one-stop ASPREE site with more news and information about the study. As it is quite a large site to navigate, we have highlighted below the most relevant sections of the site for participants, although you are most welcome to view the site in its entirety.



Above: The new ASPREE website is an easy to use resource for study participants, clinicians, researchers and the general public.

1. ASPREE NEWS:



The 'News' section on the website helps participants stay up to date on the progress of the trial. Here you will find a wide variety of ASPREE stories and announcements—from fun snippets through to radio interviews and expert responses to recent aspirin research and reports. This section (pictured above) is updated as news becomes available.

Also found under the 'News' menu are ASPREE related materials, such as ASPREE newsletters, consent forms and relevant audio and video recordings. Ita Buttrose's Community Service Announcement in which she thanks ASPREE participants can be viewed here. Feel free to bookmark this news page or email your details to aspree@monash.edu to be notified of new stories and articles in this section.

2. FOR PARTICIPANTS:

This section (pictured right) relates to participation in the ASPREE trial; what your contribution means to global health

and answers frequently asked questions about the study, study medication and enrolment. You are always most welcome to call our team about any concerns and questions.

3. PRIVACY AND ETHICS:

Discusses the trial's compliance to national ethical standards, human research ethics committees (HRECs) and protection of privacy.

4. SUB-STUDIES:

This section defines a sub-study and summarises each of the 12 sub-studies currently being undertaken in Australia. Want to know more about our aspirin and depression sub-study? This is where to visit.

The main benefit of aspree.org is that it is online to visit as often as you wish. Suggestions for news stories are most welcome.

While we do try to keep information up to date as much as possible, this website is never intended to replace health advice from your GP.



ASPIRIN IN THE NEWS

Aspirin studies and recommendations, which attracted media interest worldwide in 2015, underscore the importance of the ASPREE study to answer the big question: should healthy older people take low-dose aspirin?

Aspirin & older people Last August, the influential US Preventive Services Task Force (USPSTF) proposed that aspirin should be taken by more people to prevent cardiovascular disease and colon cancer - but only for those aged between 50 and 70 years. Outside that age range, they found insufficient evidence on the balance of benefit and risk to make recommendations.

Members of the USPSTF had reviewed available studies of aspirin and cardiovascular disease, colorectal cancer and risk factors.

The resulting draft document, which was open for public comment until October, is in direct opposition to the US Food and Drug Administration's (FDA) 2014 report that aspirin should only be taken for secondary prevention (for people who have already had a heart attack or stroke). The USPSTF are expected to release their recommendations in 2016.

Aspirin & cancer In October last year, a Netherlands observational study in 14,000 people reported that aspirin doubled life expectancy of patients with gastrointestinal cancer. The news story was based on an abstract and media release presented at the European Cancer Congress in Vienna. Unfortunately, the study had **not** undergone peer review, which is a critical verification process in academic research. Additionally, details such as age, gender, aspirin dose and duration and the stage of cancers were unclear.

New aspirin trial Most recently, a UK-led trial called Add-Aspirin commenced recruitment of 10,000 cancer survivors to discover whether aspirin prevents recurrent cancer. People living in India and the UK who have had, or are undergoing early treatment for cancer in the oesophagus, stomach, bowel, breast or prostate are eligible to participate. These cancer survivors are allocated 100 or 300mg of aspirin or a placebo tablet following or in conjunction with standard cancer treatment for at least five years. Add-Aspirin researchers plan for their findings to be published in 2026.

Results from the principal ASPREE study are expected to be published in 2018.



Friends for over 50 years, Ron Jacobson (above right) and John McCormick (above centre) were surprised to meet up at the ASPREE study update in Footscray last December. Many laughs ensued following the presentation by Melbourne Manager Dr Suzanne Orchard (above middle), assisted by study co-ordinator, Merrin Sulovski (above left).

Health & Ageing: Hunt for Genetic Link

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Funded by the NSW government (NSW Health Office for Health and Medical Research) and the Garvan Institute, the Medical Genome Reference Bank will help identify genes associated with healthy ageing.

Approximately 4,000 genomes from healthy people aged 75 years plus, without a history of cancer or cardiovascular disease, will be sequenced and analysed in this project. Genomes will come from both the '45 and Up' study and the ASPREE Healthy Ageing Biobank. Genetic information from these genomes will contribute to the Medical Genome Reference Bank, a type of 'reference library' to distinguish genetic patterns associated with good health versus genetic patterns linked to disease.

The Medical Genome Reference Bank is the first genetic profile of this calibre of healthy older people in the world. Having a 'reference library' of healthy

genes will make it quicker for scientists to identify potentially disease-causing genes outside the 'healthy' reference range. Once disease-causing genes are identified, it is possible for scientists to develop medicines and therapies to directly target that gene.

The Medical Genome Reference Bank will commence later this year and it is expected to take several years before the project is complete.

The Garvan Institute is one of the most respected genetic research facilities in the world. Research on any ASPREE Biobank sample is tightly governed by ASPREE and human research ethics committees and is restricted to highly ethical, non-commercial, public-good studies.

Genetic research is in many ways, the new frontier to help understand, prevent and treat age-related diseases such as cardiovascular disease and cancer. As scientists slowly unravel the mysteries, we acknowledge and sincerely thank all participants in the Healthy Ageing Biobank for providing the means to make these discoveries possible.

ASPREE Funding Organisations

- National Institute on Aging (NIA/NIH in the USA)
- National Health and Medical Research Council of Australia (NHMRC)
- National Cancer Institute (NCI/NIH in the USA)
- CSIRO
- Victorian Cancer Agency (VCA)

ASPREE Collaborating Organisations

- Monash University
- Menzies Institute for Medical Research (TAS)
- Australian National University
- The University of Melbourne
- The University of Adelaide
- Berman Centre for Outcomes & Clinical Research (Minnesota, USA)

Staying in touch with you is very important to us!

- Have there been any changes to your health or circumstance?
- Have feedback? We love to hear positive and constructive feedback.

Call: **1800 728 745** or email: aspree@monash.edu

Stay up to date on ASPREE at www.aspree.org

To receive 'The Tablet' ASPREE newsletter by email, send your name and email address to aspree@monash.edu or call **1800 728 745**