

# About the Optimise Study

A short orientation for GPs in participating practices

Thanks to general practices for their collaboration

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**SYDNEY**



- › This study is funded by the National Health & Medical Research Council (NHMRC)
- › It is also a PC4-supported and initiated trial with indirect support from Cancer Australia
- › Collaboration to recruit patients through primary health care clinics
- › The investigators include:
  - Prof Lyndal Trevena –University of Sydney & GP
  - Prof Jon Emery – University of Melbourne & GP
  - Prof Jack Dowie – London School of Hygiene and Tropical Medicine
  - Prof Sallie-Anne Pearson – UNSW
  - Prof Peter Rothwell – Oxford University
  - Prof Geoff Tofler – University of Sydney
  - Prof Ian Olver – University of Adelaide
  - Prof Michael Pignone- University of Texas
  - Dr Liz Barnes – University of Sydney
  - A/Prof Rowena Ivers - University of Sydney (trials coordinator) & GP



- Optimise aims to evaluate the effect of a patient decision aid for daily aspirin to prevent cardiovascular disease and bowel cancer.
- The decision aid uses personalised risk estimates and patient preferences for avoiding disease and side effects to provide some guidance about individual suitability for daily aspirin.
- All patients and their GPs will receive a brief report with their individual risk estimates – the Optimise Report. In addition to this, patients who randomised to the decision aid will receive the relevant guidance about aspirin.
- They are encouraged to have a more detailed assessment of their risks and discussion about CVD and bowel cancer prevention with their GP.
- We will phone and SMS them during the first year to find out what they decide and will also be linking to cancer and hospital datasets to follow up over the next 10 years to monitor health effects of aspirin use and non-use.



- Cardiovascular disease (CVD)
  - It has been known for some time that aspirin reduces heart and stroke events in people at higher risk but this needs to be weighed against the risk of bleeding.
- Colorectal Cancer (CRC)
  - New guidelines (Cancer Council Australia) recommend that people aged 50-70 years should actively consider taking daily low dose aspirin to prevent bowel cancer
  - The benefits for CRC only seem to occur after taking aspirin for at least 2.5 to 5 years and may not be evident until 10-20 years later
  - Life expectancy of at least 10 years should therefore be considered

Evidence-based recommendation	Grade
<p>For all people aged 50–70 years who are at average risk of colorectal cancer, aspirin should be actively considered to prevent colorectal cancer. A low dose (100–300 mg per day) is recommended for at least 2.5 years, commencing at age 50 to 70 years. The benefit may extend to older ages with longer duration of use. Benefit for cancer prevention (though shorter for cardiovascular risk) is evident only 10 years after initiation so a life expectancy of at least 10 years should be taken into consideration in the advice to use aspirin.</p> <p>The choice to take aspirin should be personalised based on age, sex and potential reduction in cardiovascular events, cerebrovascular events and thrombotic stroke. The individual should take into account the potential risks of taking aspirin. Aspirin should be avoided in patients with current dyspepsia, any history of peptic ulcer, aspirin allergy, bleeding diathesis, an increased risk of gastrointestinal haemorrhage (such as associated with use of oral anticoagulants or antiplatelet agents), or renal impairment.</p> <p>The benefit in colorectal cancer risk reduction in women over 65 is less clear cut. However, based on limited data available, older women with cardiovascular risk factors may derive a greater overall benefit than harm.</p>	B



# Recent evidence about Aspirin

## Aspirin and age

- The risks of bleeding from aspirin increase with age and are also slightly higher in men than in woman. There comes a point where the potential benefits for an individual may thus be outweighed by the risk.
- The ASPREE (ASPIrin in Reducing Events in the Elderly) study found that in *healthy older people, aged 70 or more years* low dose (100 mg) aspirin did not prolong life free of disability, or significantly reduce the risk of a first heart attack or stroke but DID increase the risk of bleeding [McNeil, J. J., et al. (2018)]. The Optimise trial does not include people 70 and older.

## Aspirin, dosage, body weight and other factors

- Daily low- dose (75–100 mg) aspirin may not be effective in people weighing 70 kg or more, particularly in those who smoked or were treated with enteric-coated formulations
- Daily 300mg aspirin may be required to achieve therapeutic levels in people weighing greater than 70kgs.
- A more tailored dosing strategy has been suggested in a recent paper in the Lancet. [Rothwell, P. M., et al. (2018)]



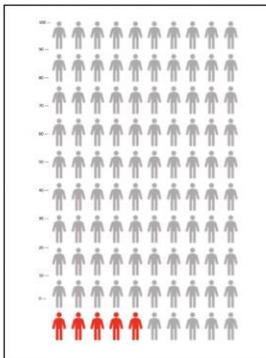
- Participants aged 50-70 are approached in the waiting room
- Not eligible if past history of CRC, bleeding history, on anticoagulants, past or current history of upper GI problems
- 10-year risk calculation – CRISP and QRISK<sup>®</sup>3 (UK)
- Intervention group Vs control
- Electronic aspirin decision aid for intervention group
- Report given to all patients and their GP for further discussion – includes their 10 year CVD and CRC risk estimates plus risk-appropriate prevention information as per Australian guidelines
- Intervention patients also receive some guidance about their potential suitability for daily aspirin
- Follow up



- Overview of patients CVD and CRC risk calculation
- Overview of patients aspirin risks Vs benefit preferences
- Personalised aspirin recommendation for intervention patients.
- General CVD/CRC information only for control patients

## Heart Disease and Strokes

Your risk of having a heart attack or stroke over the next 10 years is 5.00%  
This is your absolute cardiovascular risk and your current level of risk is considered to be *Low*



5 people out of 100 like you will have a heart attack or stroke over the next 10 years.

95 people out of 100 like you will not have a heart attack or stroke over the next 10 years.

It is recommended that people with this level of risk keep a healthy lifestyle to maintain this state.

## Bowel Cancer

Your risk of developing bowel cancer over the next 10 years is 3.00%  
This is your absolute risk of bowel cancer. Your level of risk is currently *Moderate*



3 people out of 100 like you will be diagnosed with bowel cancer over the next 10 years.

97 people out of 100 like you will not have a diagnosis of bowel cancer over the next 10 years.

It is recommended that people with this level of risk have a colonoscopy every 5 years from the age of 50, or at an age 10 years younger than the age of first diagnosis of bowel cancer in the family, whichever comes first

The most important factors for you when using the Optimise decision aid were:

Most important Avoiding having a serious bleed

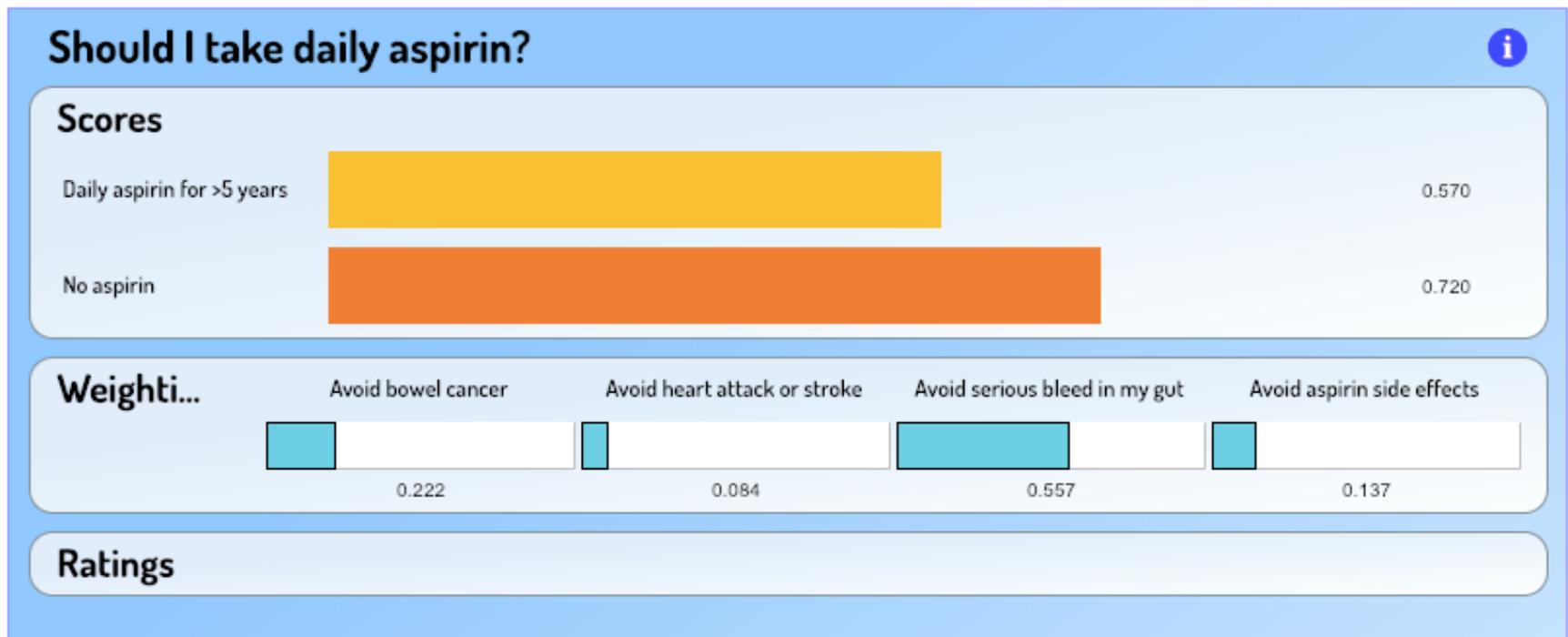
Least important Avoiding having a heart attack

**Based on your personal risk levels and what is important to you, our decision aid suggests that you consider taking daily aspirin for at least the next five years.**



# The decision aid output report

Slide the blue bars to the right for the things you most want to avoid. This page takes into account what is important for you in avoiding getting bowel cancer, heart attacks, strokes and serious bleeds in the stomach. It will provide you with a suggestion on what might be best for you. You can discuss this with your doctor.





Home

Enhanced GP Guidelines ▾

Patient Risk Calculator

GP QI & CPD Exercise

## Risk Calculator

### Most Predictive Factors

These factors must be entered to assess whether the patient is at high CVD risk

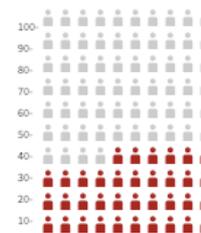
<b>Age</b> 60	<b>Gender</b> Male ▾	<b>Smoking</b> Yes ▾
<b>Blood pressure</b> Systolic 100 mmHg	<b>Diastolic</b> 70 mmHg	
<b>Cholesterol</b> Total 4 mmol/L	<b>HDL ("Good") cholesterol</b> 0.2 mmol/L	<b>ECG LVH</b> Unknown ▾
<b>Diabetes</b>	<b>Familial hypercholesterolaemia</b>	

### Risk Assessment Results

Current risk at age 60

Future risk at age 70

Risk of heart attack/stroke in the next 5 years



**36%**

This is considered within the high risk range.

Your current risk of having a heart attack or stroke in the next 5 years is 36%, which is considered high. Imagine 100 people like you sitting in a cinema. 36 of those people will have a heart attack or stroke in the next 5 years if they don't take action.

Intervention options



- › Room 121A
- › Ford Building A27
- › The University of Sydney
- › NSW 2006 AUSTRALIA
- › Telephone: +61 2 9351 7788
- › Email: [lyndal.trevena@sydney.edu.au](mailto:lyndal.trevena@sydney.edu.au)
- › Web: <http://www.sydney.edu.au/>



# ANZ Clinical Trial Registration and Ethics Approvals

- › The protocol for this study has been registered with the ANZCTR and can be found at [www.anzctr.org.au](http://www.anzctr.org.au) The trial number is ACTRN12618001219279p
- › This trial is also registered with the TGA and has been approved by the ethics committees of University of Sydney (lead) and NSW Health (data linkage) along with the Department of Health (PBS)



- › Cancer Council Australia Colorectal Cancer Guidelines Working Party. Clinical practice guidelines for the prevention, early detection and management of colorectal cancer. Sydney: Cancer Council Australia. [Version URL: <https://wiki.cancer.org.au/australiawiki/index.php?oldid=191477>, cited 2019 Jan 22]. Available from: [https://wiki.cancer.org.au/australia/Guidelines:Colorectal\\_cancer](https://wiki.cancer.org.au/australia/Guidelines:Colorectal_cancer).
- › Rothwell, P. M., et al. (2018). "Effects of aspirin on risks of vascular events and cancer according to bodyweight and dose: analysis of individual patient data from randomised trials." *The Lancet* 392(10145): 387-399.
- › McNeil, J. J., et al. (2018). "Effect of Aspirin on Cardiovascular Events and Bleeding in the Healthy Elderly." *New England Journal of Medicine* 379(16): 1509-1518.
- › McNeil, J. J., et al. (2018). "Effect of Aspirin on All-Cause Mortality in the Healthy Elderly." *New England Journal of Medicine* 379(16): 1519-1528.
- › McNeil, J. J., et al. (2018). "Effect of Aspirin on Disability-free Survival in the Healthy Elderly." *New England Journal of Medicine* 379(16): 1499-1508.
- › QRISK®3-2018 risk calculator <https://qrisk.org/three/>
- › CRISP Risk calculator <http://crisp.org.au/crisp-v3/>

