Vitamin D in your body comes from exposure to the sun or from your diet. Having enough vitamin D in your blood stream is important for maintaining healthy bones, but we don’t really know how much our bones need. Having higher vitamin D levels might also reduce risks of diseases such as diabetes, heart disease, multiple sclerosis and some cancers, **but this is uncertain**.

To fully understand the health effects of vitamin D we need to do studies with very large numbers of people. D-Health is one of the largest trials of vitamin D in the world – we are aiming to recruit about 25,000 Australians aged 60-79. The aims are to see if taking a vitamin D tablet changes the risk of a person being diagnosed with health conditions such as cancer, heart disease or infections (like flu). D-Health will give us much-needed information so we can give people correct advice in the future.
Who is conducting the D-Health Trial?

The D-Health Trial is being conducted by doctors and scientists at the QIMR Berghofer Medical Research Institute, the Queensland University of Technology, the University of Sydney, the University of Melbourne, the Menzies Research Institute and the NHMRC Clinical Trials Centre. The study is being coordinated by Associate Professor Rachel Neale at the QIMR Berghofer Medical Research Institute and is funded by a research grant from the National Health and Medical Research Council (NHMRC) of Australia.

What will being in the study involve?

If you choose to take part in D-Health you will be:

• Randomly (by chance) assigned to take a tablet containing 60,000 international units (IU) of vitamin D or a placebo (‘neutral’ tablet*) on the first day of each month for up to 5 years. We will send you a text, email or phone reminder each month. You will not know which tablet you are taking.

• Asked to complete a short survey now and for each year that you are in the study.

It is possible that we may also ask you to complete additional surveys or talk to us on the phone so that we can gather detailed information about some specific health conditions. You won’t have to take part in these extra surveys if you don’t want to.

*A placebo is a medication with no active ingredients. It looks like the real thing but is not.

Blood samples during the study

Each year we will randomly select about 600 of the 25,000 people taking part in the study and invite them to give a blood sample. This is so we can compare the vitamin D levels in the blood of the two study groups. If you are selected we will send you some extra information at that time so that you can choose whether or not you want to take part in this aspect of D-Health. (That is, you can take part in D-Health now, but you do not have to give a blood sample if invited in the future).

How will we find out details about your health?

An important component of this study is finding out information about your health. We will ask you questions about your health in our annual surveys, but we would also like to obtain information from various other sources such as:

• Hospital and pathology records.

• Existing State and National Databases such as the Australian Cancer Database, state Cancer Registries, the National Death Index and other health databases, both public and private.

• Medicare and general practice information, Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme. Medicare Australia requires you to sign a separate consent form – you can still take part in D-Health if you choose not to sign the Medicare consent form, but we would greatly appreciate your participation in this part of the trial.

We will continue to obtain information about you from health registers for up to 10 years after everybody in the trial has stopped taking tablets, unless you ask us not to.
What about confidentiality?

The D-Health Trial is bound by Commonwealth and State privacy legislation and must adhere to the guidelines of the National Health and Medical Research Council of Australia. All information collected will be treated confidentially and will be used for health research only.

All your information will be stored, analysed and reported with your identifying details removed. No information will be released in a way that would allow an individual or household to be identified, unless required by law.

Any information obtained about you during this research project can be inspected by an authorised representative of the QIMR Berghofer Medical Research Institute during routine monitoring of D-Health.

Are you allowed to take your own vitamin D tablets?

We understand that many people already take vitamin D or multivitamins that contain vitamin D, either because their doctor has recommended it or because they feel it will be good for their health. The current recommended daily intake (from foods AND supplements) for Australians is 600 IU per day, assuming no sun exposure. Most people get about 100 IU/day from food. If you take part in D-Health you can still take up to 500 IU per day (equivalent to a 1000 IU tablet every second day) as well as your study tablets.

What are the benefits of taking part in the study?

You do not have to participate in the D-Health Trial, and taking part will not necessarily improve your health. The main benefit is the satisfaction of knowing that your participation in medical research could contribute to the improved health of future generations of Australians. You will not be paid but this contribution to society comes at no financial cost to you.

To say thank you for your participation, each year you are in the trial you will have the opportunity to win one of six $200 Coles Group and Myer gift cards. We will draw one winner from each state each year and we will let you know if you’ve won.

What are the possible risks of taking part?

Vitamin D is a substance that occurs naturally in your body; you can also take it as a vitamin supplement. Too much vitamin D can cause the calcium levels in your body to become too high and this can lead to kidney stones, psychological, gastrointestinal and cardiovascular symptoms. We are giving a dose of vitamin D that is equivalent to 2000 IU/day. The United States Institute of Medicine has said that you can safely take up to 10,000 IU/day without it causing problems, but to be cautious they suggest not going over 4000 IU/day. THE DOSE BEING USED HERE IS THEREFORE WELL WITHIN SAFE LIMITS. There have been studies that have safely given doses of vitamin D up to five times higher than we are using.

People generally take vitamin D tablets daily rather than monthly and you cannot buy a 60,000 IU tablet in Australia. This is therefore considered to be an experimental dose. Studies of the way vitamin D is metabolised in the body show that a large monthly dose does not cause vitamin D levels to become too high and is very good at maintaining enough vitamin D in the blood over the whole month. There is no evidence that taking a monthly dose carries a different risk to taking a daily dose. We have chosen to give a monthly dose because it is easier for you to remember to take. Other studies around the world are doing the same thing.

The tablets also contain soybean oil. Most people with soy allergy are not allergic to soybean oil because of the way it is processed. However if you have had a severe reaction to soy in the past you should not take part in the D-Health Trial. The outside shell of the tablet contains small amounts of glycerol, gelatin and titanium dioxide.
What should you do if you have a health problem while taking part in the D-Health Trial?

While it is very unlikely that your study tablets will cause you any problems, if you have any concerns about your health you should seek medical advice just as you normally would. We will give you a card to show your doctor so that you can let them know you are taking part in D-Health.

If you suffer any injuries or complications as a result of this research project you will need to let us know. When we send your tablets, we will enclose a magnet with our helpline number on it. If necessary we will help you to arrange medical treatment. If you are eligible for Medicare you can receive any necessary medical treatment free of charge in any Australian public hospital.

Additionally, the QIMR Berghofer Medical Research Institute adheres to the Medicines Australia “Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial”; and holds a No-Fault Compensation for Clinical Trials insurance policy. If you would like to see a copy of the indemnity provided, please contact the D-Health helpline on 1300 735 920.

Future research using your information

After you have taken part in D-Health we will keep the information that you give us indefinitely. It is possible that this information will be used for future studies of health. You will not receive any notice of future uses of this information, but any future studies that seek to use your information will have to be approved by the Scientific and Ethics committees at QIMR Berghofer (and, if applicable, the institution carrying out the analysis) before they can proceed. Any information given to other researchers will be identified by a code only so that it will never be possible for them to identify you.

Can you withdraw from the study?

You may withdraw from the study at any time by telephoning, emailing or writing to us. This will in no way disadvantage you in the future. You can ask for information that we have already collected to be destroyed. You can also request us not to obtain any more information about you from health registers during our routine linkages.

Although unlikely, if you are diagnosed with high calcium or kidney stones during D-Health, we will ask you to stop taking your tablets. People who have a condition called sarcoidosis or have high levels of parathyroid hormone also need to be careful about how much vitamin D they take, so we will ask you to stop taking your study medication if your doctor tells you that you are diagnosed with either of these conditions.

Who has reviewed this research project?

All research in Australia involving humans is reviewed by a Human Research Ethics Committee (HREC). The ethical aspects of this project have been reviewed by the HREC of the QIMR Berghofer Medical Research Institute.