



A SHORT HISTORY OF THE D-HEALTH TRIAL

As the main part of the trial has finished (lots of analysis still to go!) we thought it timely to remind you of the history of the D-Health Trial. The idea to do a large trial of vitamin D in Australia was born in 2008, following discussions with experts from around the world. We knew such a trial would be challenging, and we needed to determine whether or not it was feasible. So in 2010 we obtained funding to do a 'trial run' – we recruited 644 people from across the 4 eastern Australian states and asked them to take tablets for one year. These pioneering participants helped generate important data to inform the design of 'big D-Health', and also generated some interesting scientific results (box 1). The success of this feasibility study enabled us to obtain funding for the world's second-largest trial of high-dose vitamin D. January 2014 saw the launch of D-Health and over the following 16 months we recruited 21315 people from across Australia. The last participants took their final tablet on 1 February 2020. We can't believe 6 years have gone by so quickly! We are now focused on data analysis and publication.

Publications

BOX 1: PUBLISHED MANUSCRIPTS FROM THE D-HEALTH **PILOT** TRIAL

Tran B, Neale RE et al. Recruitment and results of a pilot trial of vitamin D supplementation in the general population of Australia. *J Clin Endocrinol Metab* 2012.

Tran B, Neale RE et al. Predicting vitamin D deficiency in older Australian adults. *Clin Endocrinol* 2013

Tran B, Neale RE et al. Effect of vitamin D supplementation on antibiotic use: a randomized controlled trial. *Am J Clin Nutr* 2014

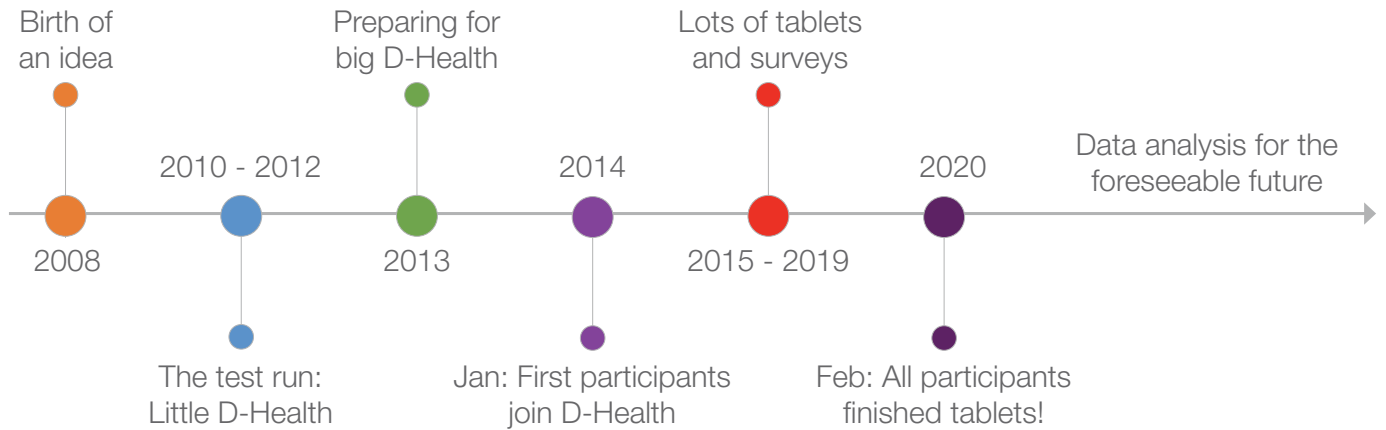


Waterhouse M, Neale RE et al. Environmental, personal, and genetic determinants of response to vitamin D supplementation in older adults. *J Clin Endocrinol Metab* 2014

Waterhouse M, Neale RE et al. Effect of vitamin D supplementation on selected inflammatory biomarkers in older adults. *Br J Nutr* 2015

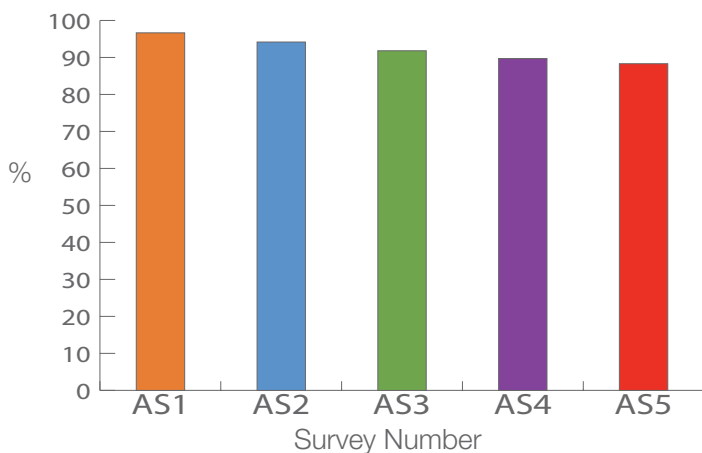
If you would like to receive copies of any of these publications please let us know.

Timeline



Survey completion

We asked you to complete surveys every year. We are extremely happy that almost 90% of participants who were originally enrolled completed the final survey (the figure below shows the percentage of people who completed the survey each year). The low percentage of missing data will help to ensure that our results are not biased.

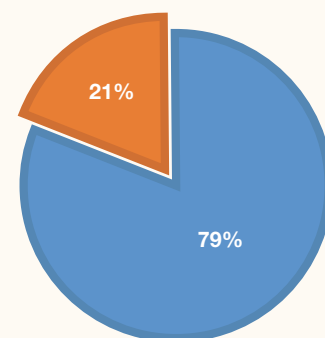


Tablet completion

Taking tablets for 5 years was a huge commitment. Most of you (79%) took the tablets for the entire study period. Of course, changes in life do occur so some people had to stop taking our tablets before the end of the study. We are grateful to everybody who contributed, even if only for a short time.

TABLET COMPLETION

■ Completed ■ Stopped early



Sub-studies

In addition to asking you to complete surveys every year, we have invited many of you to take part in sub-studies. The number invited and who took part in each of these studies is shown in the table.

Sub-study	Number invited	Number (%) who took part
Falls diary (a daily diary for 3 months to document all falls)	2615	2398 (91.7)
Cold/flu diary (a daily diary for 2 months to document symptoms of cold and flu)	3230	2740 (84.8)
Memory study (a telephone interview to assess memory and thinking)	4690	3887 (83.1)
Microbiome study (collection of stool samples to examine the bugs in the gut)	1130	835 (73.9) ^A
Blood samples (collection of blood samples, mainly to measure vitamin D) ^B	5214	3972 (76.2)

^A 111 people of the 1130 invited were ineligible to take part because of their medication use or health conditions at the time;

^B 449 people provided 2 blood samples, 27 people provided 3 blood samples, and 2 people provided 4 blood samples.

Your feedback



In our final survey we asked you to tell us what you liked, what you didn't like and what we could have done better. We haven't yet had a chance to read all your comments, but we've read through the first ~200 responses, and there are some clear themes emerging as shown in the boxes below.

A desire to help others

There were lots of comments like those below, showing your commitment to helping others.

- I liked feeling good about contribution to improved health outcomes.
- Do hope my involvement and the involvement of others will have beneficial outcomes for younger people.
- I have been proud to be involved in this study. I hope my small part will help many.

Reminder messages and overall communication

Almost everybody commented that the reminder messages were welcome and very helpful. Our staff obviously also did a great job when they talked to you for various reasons.

- I liked the ease of communication when I had questions.
- D-Health researchers were always responsive to queries and my requests.
- You were always good to me when you rang me.

Tablet type and results

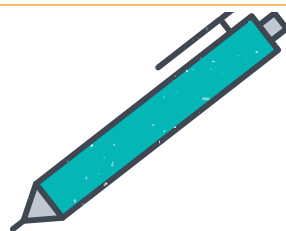
You were all very keen to find out what type of tablet you were taking. We're very glad to have been able to end the wait.

You are understandably interested in results. So are we! We are working hard and will send the first results very soon.

Overall your experience was positive

Almost all comments were extremely positive. For example:

- Very well designed and executed study – felt confident that the results would be reflective of the clear and thorough design of the study. Overall very impressed with the experience.
- I would do it again in a heartbeat.
- The five years seemed to go by very quickly. I have no complaints – it has all gone very well by my experience.



STUDY DESIGN QUESTIONS



In reading your feedback we noted that some questions about the study design. The two key questions that arose were:

How can we know if vitamin D makes a difference?

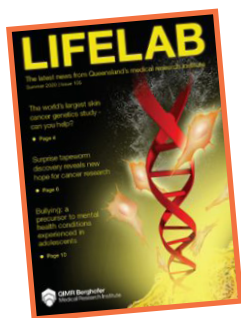
We randomly assigned people to vitamin D or placebo (essentially a computerised version of tossing a coin). This ensured that the characteristics of the two groups, on average, were the same at the start of the study. Then, during the study, the only difference between the groups was in the vitamin D level (on average, the level was 35 nmol/L higher in the vitamin D group). We will now compare the health of the groups. For example, if the proportion of people who are diagnosed with cancer differs between the two groups, we can reliably assume that this is due to the difference in the vitamin D level.

Importantly, we ensure accurate information about many health outcomes by obtaining information from databases such as Cancer Registries. In the annual surveys we have asked you about other health dimensions like your mood, quality of life, and sleep – we will compare the average scores for these items between the two groups.

We have a picture that describes the study design in Volume 5 Issue 1 of our newsletter (you can find this on our website or we are happy to mail you a copy).

How is the study valid if you haven't measured my vitamin D at the beginning and the end of the study?

The purpose of the D-Health Trial was not to see if we could change people's vitamin D levels. We already know from lots of previous research that taking a supplement causes vitamin D to increase (and we checked that this occurred in the D-Health Trial by inviting randomly selected participants to donate blood for vitamin D testing). The purpose of the D-Health Trial was to see if changing the average vitamin D level in the population would alter health outcomes. This will help policy makers to decide if more foods in Australia should have added vitamin D, or if we should recommend that all adults take a vitamin D supplement, irrespective of their vitamin D level.



The D-Health Trial involves scientists and doctors from around Australia, but the engine room of the study has been at the QIMR Berghofer Medical Research Institute. QIMR Berghofer is one of Australia's largest research organisations and conducts research across many areas, such as genetics, cancer, infectious disease, and mental health. If you are interested in learning more about our work, please visit our website (www.qimrberghofer.edu.au) where you can sign up to receive our LIFELAB magazine, or give us a call and we can organise for you to be added to our mailing list.

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