



News and information for participants in the *VITamin D and Omega-3 Trial (VITAL)*

Recent findings from VITAL

The primary aim of VITAL was to test whether supplemental vitamin D (2000 IU per day) and omega-3 fatty acids (1 gram per day) reduce the risk of cancer and cardiovascular disease. However, VITAL researchers are also investigating the effect of these supplements on many other outcomes. Here is a summary of recently published results. For the complete list of VITAL publications, please visit the VITAL website at www.vitalstudy.org.

Atrial fibrillation (AFib). AFib is an irregular heartbeat (also known as an “arrhythmia”). The four chambers of the heart normally beat at a steady rate. However, in AFib, the upper chambers of the heart (the atria) quiver or contract in a rapid, disorganized manner (fibrillation), creating an irregular rhythm. If left untreated,

AFib can increase the risk of stroke or heart failure. AFib is the most common heart rhythm problem in adults aged 65 and older. VITAL investigators, led by Dr. Christine Albert at Cedars-Sinai Medical Center in Los Angeles, found that neither supplemental vitamin D nor omega-3 fatty acids decreased or increased the risk of AFib. The omega-3 findings in particular are reassuring because such supplements, taken at much higher doses than that tested in VITAL, have been linked to an increased risk of AFib in several other studies. “Our findings do not support the use of supplemental omega-3 fatty acids or vitamin D for primary prevention of atrial fibrillation,” Dr. Albert notes. “Fortunately, they also do not show any increased risk in AFib for individuals who use these supplements at these dosages for other indications.”

Reference: Albert CM, et al. *JAMA* 2021 Mar 16; 325:1061-1073.

Age-related macular degeneration (AMD). AMD is the leading cause of irreversible vision impairment in adults aged 60 and older. The macula is the central part of the retina, the light-sensing nerve tissue at the back of the eye; it provides the sharp, straight-ahead vision needed for reading, driving and seeing fine detail. Although the causes are uncertain, the macula often wears down with age, leading to increasingly blurry central vision. Observational studies suggest that individuals with higher dietary intakes or blood levels of vitamin D or omega-3 fatty acids may have lower rates of AMD, but randomized trial data are limited. VITAL researchers, led by Dr. William Christen, examined

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From the VITAL Study Directors

Dear VITAL participant,

Thank you for your longstanding commitment to VITAL. We hope you are doing well despite the continuing challenges posed by the COVID-19 pandemic.

As announced in last year’s newsletter, we have received funding from the National Institutes of Health for continued follow-up of the VITAL study population, which means that we will continue to send you annual health questionnaires for several more years. You will receive your next follow-up health questionnaire in mid- to late January 2022. Your response is very important to us, regardless of which study pills you received in the trial and whether or not you have

had changes in your health since the previous questionnaire. The information that you provide will enhance the value of the data already collected and allow us to examine the longer-term effects of vitamin D and omega-3 fatty acid supplements and to explore other health-related topics.

Although we continue to welcome paper-and-pencil questionnaires submitted by postal mail, please note that you may instead choose to complete your annual questionnaires online via a well-established, privacy-protected web-based system. If you have already provided your e-mail address to us, we will send you an e-mail with a personalized link to a secure website where you can fill out and submit your

questionnaire. If you have not yet provided your e-mail address and would prefer the e-form option, please contact us at vitalstudy@partners.org or 1-800-388-3963.

Thank you again for helping to make the study a success. We are glad that you are part of the VITAL community!



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VITAL COVID-19 study update

In 2020, we sent a series of online surveys about COVID-19 to VITAL participants who had previously provided their e-mail addresses to us. Participants were asked whether they had been tested for coronavirus infection, had been diagnosed with COVID-19, and/or had experienced symptoms that may or may not have been related to COVID-19. Participants were also asked about the pandemic's impact on their physical and emotional well-being. Similar questions were included on the January 2021 annual questionnaire and will also be included on the January 2022 questionnaire. Taken together, the information provided will allow a deeper understanding of risk factors for, and the evolving impact of, COVID-19, including "long-haul" symptoms, in a diverse national sample of midlife and older adults. Thank you for your contributions to this important area of research.

whether supplemental vitamin D and omega-3 fatty acids protect against the development of AMD, or progression of existing AMD, and found that neither supplement was associated with these outcomes. However, the data did suggest a possible benefit of omega-3 fatty acids in reducing the risk of developing advanced AMD in persons without AMD at study entry, a finding that warrants further examination in future studies. *Reference:* Christen WG, et al. *JAMA Ophthalmol* 2020 Dec 1; 138:1280-1289.

Body weight/body composition.

Observational studies find that low vitamin D blood levels are associated with increased body weight, higher percent body fat, and with other measures of body composition,

but there are few large clinical trials investigating these relationships.

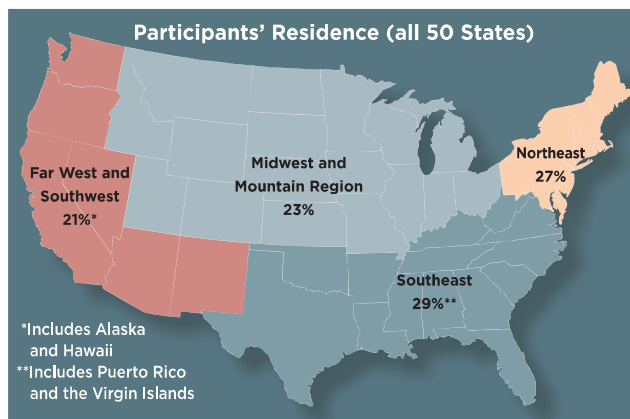
VITAL researchers partnered with Harvard colleagues Drs. Meryl LeBoff and Sharon Chou to study whether supplemental vitamin D lowers body weight or improves body composition. Body weight, body mass index (BMI), waist circumference, and

other indicators of body composition were assessed (the latter by dual-energy X-ray absorptiometry [DEXA] scan) at the start of the study and again two

years later in 771 Boston-area VITAL participants. Overall, there was no association between supplemental vitamin D and 2-year changes in weight or body composition. However, individuals with a healthy body weight (BMI below 25) assigned to vitamin D experienced a small reduction in percent body fat, whereas those with overweight (BMI 25-29.9) or obesity (BMI 30 or greater) did not derive this benefit. "The reasons for this difference are unclear but may be due to greater bioactivity of vitamin D in individuals with healthy weights," noted VITAL Principal Investigator Dr. JoAnn Manson. (A BMI calculator is available at www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm.) *Reference:* Chou SH, et al. *J Clin Endocrinol Metab* 2021 Apr 23; 106:1377-1388.

Geographic distribution of VITAL participants

More than 23,000 of the 25,871 men and women who enrolled in VITAL at its start continue to participate in the study by completing study questionnaires. The study population is geographically diverse, with participants residing in all 50 states, the District of Columbia, Puerto Rico, and the Virgin Islands. Regarding regions of the country, the percentage of study participants located in the Northeast is 27%; in the Southeast, 29%; in the Midwest/Mountain region, 23%; and in the Far West/Southwest, 21%. Also, several respondents currently live abroad, with one or more participants residing in Australia, Barbados, Canada, Columbia, Costa Rica, the Dominican Republic, Germany, Ireland, Israel, Japan, Mexico, the Philippines, and the United Kingdom.



**VITamin D and
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(VITAL Study)**

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Send us your photos and stories

Please share your thoughts about participating in VITAL and contributing to scientific knowledge about the role of vitamin D and omega-3 fatty acid supplementation in human health. We also welcome your photos and stories (travel or otherwise). We will feature a sampling of responses in future newsletters. Please write to us at vitalstudy@partners.org or the postal address in the box to the left.