



News and information for participants in the *VIT*amin D and *Om*ega-3 *Tria*L (VITAL)

From the VITAL Study Directors

Dear VITAL participant,

Thank you! Because of your commitment to the study, VITAL is now very close to answering the questions of whether vitamin D and omega-3 fatty acids (fish oil) supplements can prevent cancer, heart disease, stroke, and other health conditions. The results of VITAL are expected to play an important role in setting medical and public health guidelines on the use of vitamin D and fish oil for the prevention of these diseases. Please help VITAL fulfill its goals by continuing to take your study pills through December 31, 2017 and by completing the study questionnaires both before and after pill-taking ends. If you are not currently taking the study pills, please consider restarting them now if at all possible. For a new supply of calendar packs, please contact us at 1-800-388-3963, vitalstudy@partners.org, or the postal address on page 4.

Thank you again for helping to make VITAL a success!

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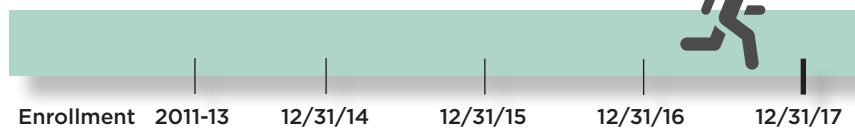


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VITAL study timeline: Final months of pill-taking!

Pill-taking Timeline



Thank you very much for your continued dedication to VITAL. The study is now in its final months of pill taking and getting very close to achieving its goal of determining whether vitamin D or omega-3 fatty acid (fish oil) supplements reduce the risk of developing cancer, heart disease, or stroke. As you know, study pill-taking will end on December 31, 2017. Here are answers to some commonly asked questions about what to expect after that date.

Will I receive a questionnaire soon after the pill-taking period ends?

Yes. In early January 2018, you will receive a short questionnaire via postal mail asking about new medical diagnoses and your compliance with pill-taking. If you have provided your e-mail address to us, we will also send you an e-mail containing a link to an online version of the questionnaire. You may choose to complete *either* the online questionnaire *or* the postal questionnaire, whichever is easier for you. (Choosing the online option facilitates the timely collection of important end-of-trial data.) As always, we are committed to protecting the confidentiality of your information and, to this end, are using a well-established,

privacy-protected web-based system for the online collection of questionnaire data.

When and how will you notify me as to which type of study capsules I have been taking?

Soon after we receive your completed short questionnaire, we will send you a letter stating whether your study capsules contained active vitamin D, active omega-3 fatty acids (fish oil), or placebo.

When and how will I be notified of the study's findings?

We will analyze the data and submit a manuscript with the study's main findings to a major medical journal. Upon publication of the manuscript, we will send you a letter or newsletter describing the study's main findings. Although the timeline is not certain, we anticipate that the main results will most likely be available sometime in 2018.

Other than the short questionnaire to be sent in early January 2018, will you be sending me additional questionnaires?

Yes. In fall 2017, you may receive a brief questionnaire asking whether you have

VITAL on the Go

Ligaya U., of Florida, writes, “I hope I have made a contribution to ... and help[ed to] impact ... health. ... [M]y husband and I have been dance partners for over twenty years. We also love to travel and enjoy three beautiful grandchildren.”



Joel S., of California, at Taiohae, Nuku Hiva, in French Polynesia.



In 2016, **Mildred F.**, of Maryland, received the U.S. President’s Lifetime Achievement Award (signed by President Barack Obama) for her “lifelong commitment to building a stronger nation through volunteer service.” Her 18,000 volunteer hours of community service were documented by one of her grandchildren.



Margaret S., of Maryland, visited Peru and Ecuador in April 2016. She writes, “I managed to take my pills every day while touring part of the Amazon, climbing to Machu Picchu [pictured], touring the Galapagos Islands and learning a lot about the culture and people of both countries.”



Peg W., of Massachusetts, at Mackinnon Pass, the highest point on New Zealand’s Milford Track.

Jonathan H., of Oregon, at Cape Horn, Chile, writes, “The negative space in the iconic sculpture (which has blown over a few times!) represents an albatross.” (In this photo, only the bottom wing is visible.) He adds, “I’m proud to say I have never missed a day with my capsules since I started the study and they have been all over the world with me.”



Participant Perspective

What does VITAL mean to me?

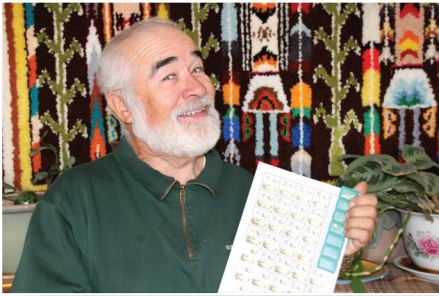


Virginia D., of New York, visiting 868 Estate Vineyards in Purcellville, Virginia, in October 2016.

“Medical trials are a major tool in advancing preventive medicine knowledge. Pulling out my pill pack while traveling is a great conversation starter.” **Will W.**, of Texas, at the Cuban Presbyterian Church National Activity Center near Santa Clara, Cuba.



“We are pummeled daily with dietary advice based on hunches, wishful thinking, anecdotal evidence, and plausibility arguments. This profusion of dietary fads reflects our society’s intense hunger for nutritional wisdom. The only known reliable source for the desired knowledge, though, is carefully conducted, placebo-controlled trials like the VITAL study. Such studies require a huge amount of work, but if someone else is willing to take on all the challenges of organization, funding, logistics, analysis, and so on, I’m delighted to do my small part to contribute to the production of one modest nugget of scientific gold-standard nutritional knowledge. It is, after all, the only way to make progress.” **Peter P.**, of California



Joseph V., of California.

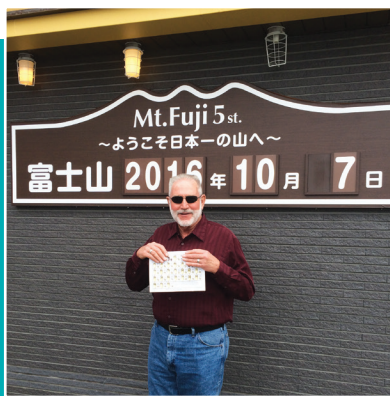
“I decided to join the VITAL study because I understand the importance of doing clinical studies. I worked as a clinical research nurse at a major teaching hospital in Chicago for over 20 years. I encourage my family and friends to participate in any clinical trials they can. Even if you receive a placebo, you are helping future patients by the information the study receives for control information.” **Helene L.**, of Illinois

“I have been proud to be in the VITAL study, and every time I see references to it in other publications, I am thrilled to be able to say, ‘Wow, that’s what I have been doing for these years.’ I appreciate all your work and efforts to keep us up to date on progress. I am so looking forward to reading the final document. I currently work in a small county health department where women present with a variety of health problems. I hope that what we have been doing will provide guidance for helping them as well.”

Lorraine M., of North Carolina

“I chose to participate in the VITAL study because, as a health-care professional, too often I see treatments ordered or at least suggested based on prior practice but not on documented research. I would like to know unequivocally whether it is efficacious to order vitamin D and/or fish oil for my patients. In my opinion, this study will answer those questions and I am honored to be a part of it.” **Margaret P.**, of Massachusetts

“For years my doctor kept saying, ‘But there have been no large double-blind studies on....’ whatever supplement I ask him about. The VITAL Study, [which I] started with my doctor’s permission, allowed me to be a part of the process. Also, the involvement of Brigham [and Women’s Hospital] and Harvard provided confidence that this was a very serious project.” **Richard D.**, of Virginia



Sam W., of Pennsylvania, at the summit of Mt. Fuji in Japan.

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FOR A SAMPLING OF ADDITIONAL COMMENTS, SEE WWW.VITALSTUDY.ORG.

Participant Perspective (continued)



“I am a strong believer that clinical trials are the only way to develop new methods for both disease prevention and cure. My estimate is that I may have missed maybe 2 days of the study meds during my participation in [VITAL and an earlier trial]. Having worked so long and hard in my nursing career, recruiting subjects for clinical trials myself, I was seriously committed to being a good research subject.”

Lynn C., of New York

“I was motivated to participate in the VITAL study because I felt that I would be contributing to important research on disease prevention. I worked with older adults as a social worker and was dismayed at the number and cost of medications most of them were taking. There seems to be so much focus on treatment and too little on prevention. I have tried to use healthy diet, exercise and natural supplements to maintain my own health, so I was excited to help with such a long-term comprehensive research project using vitamin D and fish oil. I definitely want to continue to the end of the study and hear the findings. I am also curious to find out if I have been taking the placebo or the supplements. I have faithfully taken my pills for 5 years, and they went with me on trips to Alaska, the Caribbean, the Baltic Sea and many states. I haven't had any problems with the pills and no major health issues. I also have appreciated being able to easily reach someone by phone at the study if I had any questions and getting the newsletters. I wish you much success with the study and look forward to hearing more.” **Marion W.**, of Florida

“I joined VITAL because I thought it would be interesting to participate in a real scientific study to see how it works from the inside, and also because I felt good about doing some small part in adding to the body of knowledge regarding possible preventive measures for cancer, stroke and heart disease. Even if it turns out that, no, neither vitamin D nor fish oil have any beneficial impacts in preventing those diseases, at least it will put to bed any questions, and allow research dollars to be spent looking elsewhere.” **Douglas B.**, of Massachusetts

“My motivation for taking part in the VITAL Study is quite simple, merely a desire to be of assistance in the search for information that will hopefully benefit folks like myself, older people who wish to do everything they can to prolong a healthy life.” **Bill W.**, of Illinois

“As an African American, I wanted to participate in the study, to contribute to the understanding of the ways to prevent certain diseases. I know that African Americans are often underrepresented in such studies.”

Delores N., of Illinois

“At the time I signed up I had no concept of the length of the study nor much of an understanding of its importance. As the study went on, I came to better understand the commitment I had made and the good it could do. Now that it is coming to an end, I appreciate having had the chance to be a part of something that could lead to helping others in the future. I am proud of myself for sticking with the program and taking those 2 pills every day. I must admit, I will miss the pills and the small daily routine of taking them. Thanks for the chance to be part of the study, I enjoyed it.” **Roger M.**, of West Virginia

— *TIMELINE continued from page 4* —

experienced any of the major health outcomes under study. Additionally, we will send you two regular-length health questionnaires—one in 2018 and one in 2019. The supplemental information gathered on these questionnaires will be important to address the long-term health effects of the VITAL interventions and will also allow for exploration of new hypotheses regarding health promotion and disease prevention.

Results of Design-a-Birthday-Card Contest

Thank you to everyone who submitted an entry to our Design-a-Birthday-Card contest! The winning designs are now being featured on the birthday cards that we send to VITAL participants. These designs have also been posted on the VITAL website, www.vitalstudy.org.



A Call for Photos

We continue to enjoy receiving photos of VITAL participants. If you like, please send us a photo (digital preferred) of you with your calendar pack, along with a note describing where the photo was taken, as well as any reflections about your participation in VITAL. Although we cannot publish all photos, we will include as many as possible in future newsletters.



**VITamin D and
OmegA-3 TriAL
(VITAL Study)**

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