



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

We Can't Do It Without You!

The continued participation of each member of VITAL is essential to answer the important question of whether midlife and older adults should consider taking vitamin D or omega-3 fatty acids (fish oil) supplements to prevent cancer, heart disease, and stroke. As detailed in previous issues of *VITAL Signs*, some studies suggest that this may be the case, but available results are far from definitive. It remains unclear whether taking supplemental vitamin D or fish oil can lower the risk of developing cancer or cardiovascular disease—and whether any benefits are offset by potential risks.

Many health care providers are encouraged by preliminary data on

vitamin D and fish oil supplements and are already prescribing these supplements for their patients. Unfortunately, given current limitations of medical knowledge regarding these supplements, health care providers are acting not on established facts but only on educated opinions on how best to treat patients. Many times in the past, educated opinions based on promising preliminary data did not hold up when rigorously tested in large randomized clinical trials. This is why your participation in VITAL is so important. VITAL is the largest clinical trial of vitamin D and fish oil in the world and the only trial designed to provide clear answers as to whether

these supplements benefit a diverse group of U.S. men and women—people with characteristics similar to yours.

Each participant who continues to take his or her study capsules and completes the study questionnaires strengthens VITAL's ability to detect beneficial and/or harmful effects of vitamin D and fish oil supplements (if such effects exist). The continued dedication of participants assigned to placebo is equally critical to that of participants assigned to active supplements. It is only by comparing the health outcomes of people on active supplements to those of people on placebo that VITAL will be able to

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From the VITAL Study Directors

Dear VITAL participant,

As you know, the VITAL study was designed to answer the critically important questions of whether vitamin D and/or omega-3 fatty acids (fish oil) prevent cancer, heart disease, and stroke. Thanks to your commitment to take the study capsules and fill out the study questionnaires, we are well on our way to answering these questions.

We are extremely pleased to report that we have successfully asked the National Institutes of Health (NIH) to continue to fund VITAL. The first phase of the study focused on enrolling a large, racially/ethnically diverse, and dedicated cohort of U.S. men and women willing to commit to taking the study capsules and fill out annual study questionnaires.

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Thank you for your support of VITAL!

Dr. JoAnn Manson has prepared a short video presentation to thank you for your ongoing participation. The video can be viewed on the study's website, www.vitalstudy.org.

VITAL Q&A

Q. I did not provide an optional blood sample at the start of the study. Did this affect the study group to which I was assigned? What is the likelihood that I am taking at least one “real” study supplement rather than placebo?

A. All participants, whether or not they provided a blood sample, had an equal chance of being assigned to each of the four study groups: (1) daily vitamin D and fish oil (25% chance); (2) daily vitamin D and fish oil placebo (25% chance); (3) daily vitamin D placebo and fish oil (25% chance); or (4) daily vitamin D placebo and fish oil placebo (25% chance). There is therefore a $25+25+25=75\%$ chance that you are taking at least one “real” supplement.

Q. Can I complete the questionnaires by telephone if I have a vision problem? My vision has been getting worse over time, making it difficult to read the yearly questionnaires.

A. Yes. Participants who for medical reasons cannot fill out their paper questionnaires should feel free to contact us to request a phone-administered questionnaire. However, we do ask that participants who are medically able to do so continue to fill out paper questionnaires.

Coming Soon: A New Look for the Large Study Capsules

The manufacturer of the large study capsules, which contain either omega-3 fatty acids (Omacor® fish oil, 1 gram) or placebo, will be changing the color of the capsules from a reddish brown to a more transparent amber color. Please note that the formulation and dose of the study ingredients contained in the capsules will remain the same, as will the size of the capsules. If you were originally assigned to fish oil when you entered the study, you will still receive fish oil. If you were originally assigned to placebo, you will still receive placebo. As before, the fish oil and placebo capsules will look the same as each other. The transparent amber capsules will start shipping in February 2015. You should expect to receive your first shipment of calendar packs containing the transparent amber capsules sometime between February 2015 and February 2016. The label on the aluminum pouch that encloses the calendar packs will highlight the color change. You will not receive the transparent amber study capsules until you are due for a new shipment of calendar packs. In the meantime, please continue to take your current supply of study capsules. Thank you!



Current (left) and future (right) look of the large study capsules

VITAL Updates Between Newsletters

In addition to printed newsletters, which will continue to arrive at your designated postal address on a regular basis, we'd like to send you additional updates on study-related news when we think it would be of interest to you. Because it's quicker and more cost effective to send these communications by e-mail rather than postal mail, we'd appreciate it if you would consider providing your e-mail address, if you have one and have not already sent it to us. Just drop us a line at vitalstudy@partners.org. (Your e-mail address will be used ONLY by VITAL and VITAL substudies. It will not be shared with other groups within Brigham and Women's Hospital or with any outside groups, and it will not be sold to any commercial enterprises.) Please rest assured, however, that we'll keep you updated on any important news, whether or not we have your e-mail address.

VITAL on the Go

Why Our Participants Joined VITAL



“I’m health conscious and thought that being in this study could help me rather than hurt.”

— Wanda P. of Pennsylvania recently took a cruise in Asia. Ports of call included Singapore, Thailand, Vietnam, and Hong Kong.



“I am participating in the VITAL study because it is important to expand our knowledge of nutritional recommendations that are science based. In my opinion, far too many people are spending money on nutritional supplements that are useless, if not harmful. Consumers need information so as to make the best decisions regarding their health.”

— Dave S., PhD, of California, at Uluru (also known as Ayers Rock) in central Australia.



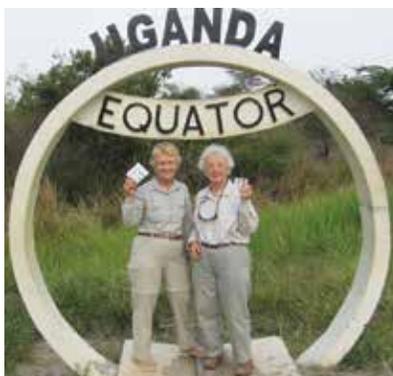
“What motivated me to participate in VITAL is a great and rare opportunity to make an enormous contribution and to show my sheer excitement about getting answers to the question of whether vitamin D and marine omega-3 fatty acids (fish oil) can reduce the risk for cancer, heart disease, stroke, and many other illnesses.”

— Jose B., CPA, of Illinois, at the Eiffel Tower in Paris, France



“I volunteered for this trial because I felt I was in the range of those who could have a heart attack from either being an African American or [having] hereditary [factors]. But, more so, I volunteered in order to contribute something to my fellow human beings. There is a saying, ‘When you help someone, it may be the one to save your life.’”

— Emmanuel N. of Illinois



“I think that it’s important for people to participate in studies that provide an evidence base for what we do. ... My sister and I were in [a] previous study for 10 years because it was a good thing to do.”

— Shannon P.

— Sisters Shannon P., RN, PhD, FAAN, of Arizona (left), and Joan V., MS, of Florida (right), on safari in Uganda in February 2014. A stop at the Equator offered an ideal photo opportunity.

“If there’s no harm to me, I thought I could do good for somebody else.”

— Joan V.

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This phase of the study reached its goal earlier this year with the enrollment of our 25,875th participant. In giving us the green light to continue the study, the NIH praised the high level of commitment demonstrated to date by study participants; the careful design and progress of the study; and the high scientific impact of the eventual results. (Indeed, our proposal received the best possible score for NIH funding!) The trial, in which participants will take their study capsules for an average of 5 years, is expected to provide findings that can be translated into clear guidelines for the general public and clinicians about who should (or should not) take vitamin D and fish oil supplements to prevent cancer, heart disease, stroke, and other health problems. Many patients and their doctors want to know if taking vitamin D or fish oil supplements at midlife or beyond will help them lead healthier lives.

Thank you so much for your hard work to date and for your continued participation in VITAL. If you have any questions, please do not hesitate to contact us at 1-800-388-3963 or vitalstudy@partners.org, or by postal mail (see our address below).



**VITamin D and
Omega-3 Trial
(VITAL Study)**

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conclusively determine if differences between these groups are due to the supplements.

It may reassure you to know that the health outcomes of study participants are closely monitored by a panel of independent medical and statistical experts. If the panel were to find that one of the treatment groups was doing much better or worse than the others, you would be notified as soon as possible so that you would be able to change your supplement regimen.

We wish to congratulate and thank all VITAL participants. We would also like to make a special appeal to those of you who have stopped taking your study capsules and/or have started taking vitamin D or fish oil supplements on your own. If you are medically able to do so, we ask that you consider restarting the study

Each participant who continues to take his or her study capsules and completes the study questionnaires strengthens VITAL's ability to detect beneficial and/or harmful effects of vitamin D and fish oil supplements. . .

capsules and, if applicable, stopping outside use of vitamin D or fish oil supplements. This will maximize the chance that VITAL finds conclusive

answers as to whether the supplements prevent cancer and cardiovascular disease. If your physician feels strongly that you should be taking vitamin D or fish oil, please call or e-mail to let us know (if you have not already done so) and also report the outside use on your next study questionnaire. In most cases, it is safe to continue taking your study capsules in addition to the supplement prescribed by your doctor. We would be happy to provide your doctor with current information on the uncertain

role of vitamin D and fish oil for prevention of cancer and cardiovascular disease, and explain why your continued participation is crucial to the success of VITAL.

How do you remember to take your study capsules every day?

Please let us know by writing to vitalstudy@partners.org or the postal address listed at the left (and feel free to include a photo of you with your pill pack). A sampling of responses will be included in a future newsletter.