



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

## Reminder: VITAL study timeline

As announced in the last newsletter, study pill-taking will end on December 31, 2017. Thank you for your continuing collaboration as VITAL approaches this milestone and gets closer to determining whether vitamin D or omega-3 fatty acid (fish oil) supplements reduce the risk of developing cancer, heart disease, or stroke. Here's a reminder of what's ahead:

- Normal follow-up procedures will be in place throughout the coming year. We will continue to mail you

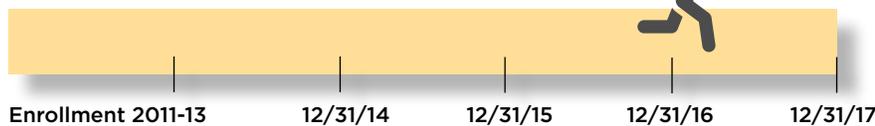
annual follow-up questionnaires about your health, and to send calendar packs with enough study pills to last through December 31, 2017.

- When the pill-taking period ends, we will mail you a short questionnaire to collect information on new medical diagnoses and your compliance with pill-taking.
- Once we receive your completed short questionnaire, we will notify you by mail as to whether your study

capsules contained active vitamin D, active omega-3 fatty acids (fish oil), or placebo.

- We will analyze the data and submit a manuscript describing the study's main findings to a major medical journal. When the manuscript is published, we will send you a letter or newsletter describing the study's findings.
- We will send you two additional annual health questionnaires—one in 2018 and one in 2019. These supplemental data will help address the main research questions around which VITAL was designed and will also allow for exploration of new hypotheses regarding health promotion and disease prevention.

### Pill-taking Timeline



### From the VITAL Study Directors

#### Dear VITAL participant,

**Thank you!** As VITAL nears its final year of pill-taking, we would like to express our gratitude for your extraordinary dedication to this important research endeavor. With your help, VITAL is now close to achieving its goal of determining whether vitamin D and omega-3 fatty acids (fish oil) can prevent cancer, heart disease, stroke, and other health conditions. VITAL is one of only two large (more than 10,000 participants) randomized clinical trials of vitamin D in the world for the prevention of cancer, heart disease, and stroke—and the only such trial in a racially and ethnically diverse study

population. It is also the only large trial of fish oil supplements in a generally healthy population. As such, its results are expected to shape medical and public health guidelines regarding the use of vitamin D and omega-3 fatty acid supplements for prevention of cancer, heart disease, stroke, and other medical conditions. Please help VITAL achieve 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. Thank you again!

**And an appeal ...** We also have a request for those of you who have stopped taking the study pills. If you are medically able to

do so, we would very much like for you to consider restarting the study pills at this time. Higher pill-taking rates will help to ensure that VITAL achieves its goals. If you wish to resume taking the study pills and need calendar packs, please contact us at 1-800-388-3963, vitalstudy@partners.org, or the postal address on page 3.

**JoAnn Manson, MD**  
Professor of Medicine  
Harvard Medical School  
Brigham and Women's  
Hospital



**Julie Buring, ScD**  
Professor of Medicine  
Harvard Medical School  
Brigham and Women's  
Hospital



# Participant Perspective

## What does VITAL mean to me?

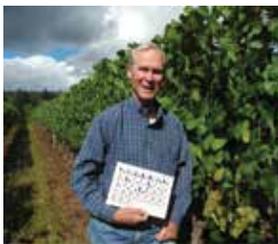
“I decided to participate for several reasons: (1) I have tremendous respect for the organization/hospital that sponsors the study, and knew I could trust the researchers’ reasons and methods, (2) I was taking no supplements or vitamins because OTC [over-the-counter] supplements are confusing and so often contain additional ingredients that cause me stomach problems, so decided I might as well try some (or one or none as they could be placebos) from a reputable source, and ... (3) I support the efforts for women’s health information being done through VITAL. If omega-3 and/or vitamin D can be shown to assist our resistance to stroke, heart disease, and/or cancer (or not), I will be proud to have been a part of those valuable findings.” **Virginia B.**, of Ohio, at a flower sculpture garden in Santa Clara, Cuba



“I have a scientific background and am generally appalled by small studies whose results are overblown in news reports and over-believed by both lay people and many doctors. This is particularly true in nutrition and supplement studies. ... Thus, I was pleased to volunteer for a study with sufficient robustness that I could believe the results—as my contribution to science. I’m waiting, with great curiosity, for the results.” **Lita N.**, of Massachusetts

“The reason I decided to participate in the VITAL study program was simply for the satisfaction of knowing I could play a part in an effort to advance mankind’s knowledge.” **George P.**, of Nevada

“As a former biomedical researcher, I understand the importance of adherence to research protocols. Toward that end, I am pleased to say that I have not missed a single dose, even while traveling, during my years of participation in the VITAL study. From [this] photograph, you will also understand why I consider a sip of wine every day part of my medicinal regimen.” **David B.**, of Oregon, in his vineyard



“I started the VITAL Study 5 years ago when I read that there is very little research into cancer in African-American women. Very few African-American women engage in the types of research studies used to determine how cancer ... develop[s] and especially how to prevent cancer. ... The time on this study has gone by very fast as taking the required pills became a part of my daily life. I am very pleased to know that because of my consistent efforts to take the pills and remain a part of the VITAL study, research has continued towards the prevention of cancer and possibly other diseases. I am very proud to be a part of this study and I sincerely pray that this study will be valuable for our generation, for future generations, and especially for African-American women.” **Theresa S.**, of Virginia

“I wanted to participate in the VITAL study because the males in my family have a history of coronary artery disease. It is my hope that in some small way my participation in the VITAL study will help others prevent heart disease.” **Bill W.**, of Texas

“Participating makes me feel that I’m contributing data that could help people in the future.” **Thomas O.**, of New York

“I am interested to know if taking vitamins and supplements really make a difference. My husband and I disagree. He takes several OTC [over-the-counter] vitamins. I don’t. I asked my doctor when I first received your information what he thought. He said if I was interested go ahead. He is also interested in the results.” **Anthea P.**, of Georgia

“I have been committed to my participation in the VITAL study because of its design, breadth, and execution. Through the enrollment process, including blood samples, daily consumption of study capsules, periodic memory testing, and communication from VITAL’s leaders, I’ve felt very involved, informed, and dedicated to upholding the promise of the study. I look forward to knowing what has been learned once results have been assessed and published.” **Peter S.**, of Kansas

“Research studies are a way to learn what works and what doesn’t, so I was very willing to participate when asked to take part in VITAL. Being diligent in adhering to the daily pill routine has not been difficult as I recognize the need for good data. I also respect the fact that conducting a broad-based, long-term study such as this is expensive.” **Mall B.**, of Washington

“I think this study is important because of all the conflicting information you hear from advertisements to word-of-mouth advice from well-meaning friends and relatives. I don't like spending money for pills that may not have any benefit. I know people who spend lots of money for pills which they believe are necessary for good health.” **Steven C.**, of Ohio

“Heart disease, stroke, and diabetes are a problem for African Americans and others as well. I am glad to be a participant in a study that might contribute to finding a cure for these diseases or to controlling them with a better understanding of how these diseases affect people regardless of ethnicity. I am taking my meds as directed.” **Larry H.**, of Mississippi

“Like so many others, I know someone with cancer. The toll on our loved one, as well as the rest of us, has been devastating. If my taking two pills a day for five years can make even the tiniest difference in finding a cure, it is an honor and privilege to do so.” **Carrie H.**, of Kansas

“As a biostatistician, I was often involved in the design and analysis of randomized trials. I welcomed the chance to be ‘on the other side’ for a change, with VITAL. ... I am interested in learning the study results and think that they should be ‘the last word’ on this question because the sample sizes are so large. It's also been fun to see how the VITAL staff encourage continued participation. I, of course, will keep it up to the end because my taxpayer dollars will have been wasted if enough participants don't continue until the final assessment.” **Paula D.**, of Washington. (Using data from a 20-year study of 6,000 older adults, Paula developed a “healthy life calculator”—available at [healthylifecalculator.org](http://healthylifecalculator.org)—that can help people aged 65 and older predict their number of remaining healthy and able years.)

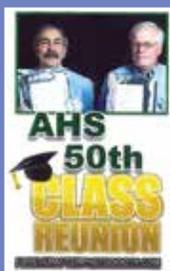


## VITAL on the Go



**Beverly M.** and friend **David R.**, of Massachusetts, were talking at the park one day and discovered that they were both VITAL participants.

**Fred M.**, of Pennsylvania (on the left), and **Tom M.**, of Texas, posed with their pill packs at their 50th high school reunion in Illinois in July 2016. Fred writes, “Tom and I were decidedly surprised, when during his visit to our house [the year prior], he excused himself to take the same study pills I have consumed since 2012!”



**Paul M.**, of Connecticut, travels widely with Daisy the Pig and two pugs to present ‘Pig Out on Reading’ programs to children. He writes, “I wanted to thank you for being flexible enough to alter where my [study] pills go each year as we are on the road about 10 months of the year!”

## Calling all artists: Design a birthday card for your fellow VITAL participants!



Do you like to draw, paint, take photos, or use the computer to create art? If so, consider submitting your original artwork/design to be featured on the birthday cards that we send to VITAL participants. Beginning in early 2017, we will select up to 12 designs—one design per month—for the birthday cards that we send to participants throughout the year. If your entry is one of the chosen designs, approximately 2,000 VITAL participants throughout the U.S. will receive a card featuring your artwork. We will acknowledge all submissions, and we will also let you know if your design has been selected. In addition, we will post the winning designs on the VITAL website.

### Contest guidelines:

- Please submit all artwork in electronic form. High-quality digital photos or scanner-generated electronic files of your artwork are preferred.
- No more than two entries per participant.
- Deadline for submission: **February 1, 2017.**



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

900 Commonwealth Avenue, Floor 3  
Boston, Massachusetts 02215  
Telephone: 1-800-388-3963  
E-mail: [vitalstudy@partners.org](mailto:vitalstudy@partners.org)  
Website: [www.vitalstudy.org](http://www.vitalstudy.org)

## Sleep and heart health

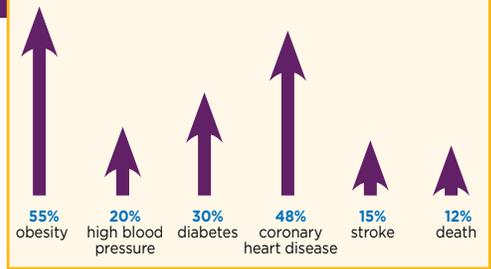
**H**ow much sleep do you need? Although physiologic sleep requirements vary from person to person, many authorities recommend that midlife and older adults get 7 to 8 hours of sleep per night for optimal health and functioning. The percentage of Americans failing to meet this guideline has been creeping up in recent decades, rising from about 22 percent in 1977 to 29 percent in 2009. This is concerning, because not getting enough sleep can negatively affect cardiovascular health, according to the American Heart Association's (AHA) first-ever scientific statement on sleep, released earlier this year.<sup>1</sup> Based on its review of the scientific literature, the AHA concluded that, compared with those who habitually sleep 7 to 8 hours per night, adults who sleep fewer than 7 hours per night are at increased risk for obesity, high blood pressure, diabetes, coronary heart disease, and stroke. What accounts for these relationships? One of the many reasons is that short sleepers are more likely to overeat and to consume an unhealthy diet, with less food variety, more calories from snacks and fewer from main meals, and greater intakes of sugar, caffeine, and alcohol. Though the data are not entirely consistent, experimental studies also show that sleep restriction unfavorably affects blood sugar processing, heart rate

variability, and blood vessel dilation, and increases inflammation and stress hormone levels.

The AHA also found evidence linking two specific sleep disorders—insomnia and obstructive sleep apnea—to an increased risk for diabetes and cardiovascular disease. About 30 to 45% of adults—and an even higher percentage of those aged 65 and older—report symptoms of insomnia, and 17% of men and 9% of women aged 50 and older have sleep apnea. Symptoms of sleep apnea include habitual loud snoring, with intermittent pauses in breathing, possibly followed by choking or gasping. If you suspect these symptoms (ask your bed partner), please consult your healthcare provider, as diagnostic tests and treatments for sleep apnea are available.

In addition to cardiovascular consequences, insufficient sleep has also been linked to impaired learning and memory formation, decreased attention span, and reduced decision-making ability; irritability and depression; greater susceptibility to infection; motor-vehicle and other accidental injuries; and, possibly, lowered survival after a cancer diagnosis. A 2010 analysis of 16 studies involving 1.4 million participants followed from 3 to 25 years concluded that short sleepers have a 12% higher risk of premature death.<sup>2</sup>

### Increased Risks for Short Sleepers



On the flip side, too much sleep may also be bad for your health. Studies show that sleeping 9 or more hours per night is associated with an increased risk for obesity, diabetes, and heart disease, as well as a 30% higher risk of death.<sup>2</sup> However, as noted above, people do differ in the amount of sleep they need, and genes have been found to influence an individual's sleep requirement.

If you aren't getting the sleep you need, consider trying (or retrying) these tried-and-true sleep-promoting strategies: maintain a fixed sleep and wake schedule, with no daytime naps; keep a quiet, dark, and cool bedroom; and avoid caffeine, alcohol, smoking, exercise, screen time, and stressful personal interactions too close to bedtime. For more information, check out the National Sleep Foundation's website at [sleepfoundation.org](http://sleepfoundation.org); the Sleep Education website of the American Academy of Sleep Medicine at [sleepeducation.org](http://sleepeducation.org); and the Healthy Sleep website produced by Harvard Medical School and the WGBH Educational Foundation at [healthysleep.med.harvard.edu](http://healthysleep.med.harvard.edu).

#### Sources:

1. *Circulation* e-publication 2016 Sep 19
2. *Sleep* 2010; 33:585-592.

### New option: Annual study questionnaires can now be completed online!

Although we continue to welcome paper-and-pencil questionnaires submitted by postal mail, we are excited to announce that VITAL participants may now choose to fill out and submit their annual questionnaires online. If you prefer the e-form option for your next annual questionnaire, please contact us at [vitalstudy@partners.org](mailto:vitalstudy@partners.org) or 1-800-388-3963, and we will send you an e-mail with a personalized link to a secure website where you can complete and submit this questionnaire. 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.