



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

VITAL Team Walks for Heart Health

On a bright and clear Saturday morning in September, a group of VITAL staff members at Brigham and Women's Hospital participated in the American Heart Association's annual Heart Walk. The Walk consisted of a six-mile loop around the Charles River in Boston, and friends and relatives of the VITAL team came out to support the event. The VITAL team raised more than \$1,000 for the American Heart Association.

The inspiration for the VITAL team's participation in the Heart Walk is the strong commitment that the study participants have shown to the trial. "Nearly 26,000 men and women across the country have joined VITAL and given their time and energy to advance scientific understanding of ways to prevent heart disease, stroke, and cancer," said Dr. JoAnn Manson, one of VITAL's Study Directors. "What better way to honor their contributions than for the staff to walk together as

a team to support the American Heart Association's efforts to combat cardiovascular disease?"

"I have been fortunate enough to work on a daily basis with the participants in the study, and it has been a real honor," said David H., the VITAL research assistant who first proposed the idea of VITAL staff and researchers participating in the Heart Walk.

"The first-ever VITAL Heart Walk was an enormous success," concluded Dr. Manson. "Though more time and research is needed to better understand and prevent heart disease and stroke, the VITAL team's participation in the Heart Walk is a testament to the fact that the heart of VITAL, both among the staff and the



▲ Team VITAL: Front row (L to R): Allison, Meg, Jahi (Kerry's son), Eileen, Denise, Julie. Back row (L to R): Sara, David, Tom, Joshua (Dr. Manson's son), Dr. J. Manson, Kerry, Georgina, Ali, Montgomery, Moorthy, Xiaorong, Viviane.

participants, continues to beat strong."

Heart disease and stroke are the number one and number five most common causes of death in the United States. The VITAL study is testing whether vitamin D and omega-3 fatty acid supplements can help prevent these diseases, along with cancer, the second leading cause of death in the United States.

From the VITAL Study Directors

Dear VITAL participant,

Thank you for your continuing collaboration on VITAL. *As a small token of our appreciation, we have enclosed a gift—a keychain with attached flashlight—in this newsletter mailing.* We hope that you find it useful.

VITAL is well on its way to answering the question of whether vitamin D and omega-3 fatty acids (fish oil) can prevent cancer, heart disease, stroke, and other health conditions.

It may interest you to know that VITAL is one of just two ongoing large-scale (10,000 or more participants) randomized clinical trials of vitamin D for the prevention of cancer, heart disease, and stroke in the world—and the only such trial in a racially and ethnically diverse study population! The other ongoing large trial, dubbed D-Health, is taking place in Australia. In the D-Health trial, 21,000 men and

— continued on page 2



JoAnn Manson, MD

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



Julie Buring, ScD

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

VITAL Q&A

Q. I would prefer to complete the annual health questionnaires online rather than in paper-and-pencil format. Is this possible?

A. Yes! 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. The online option is available beginning in November 2015. The cover letter accompanying your next annual questionnaire will provide detailed instructions regarding online submission. In the meantime, if you have received but not yet filled out your latest annual questionnaire and would like to do so online, please send us an e-mail at vitalstudy@partners.org. Within 5 days, we will send you an e-mail response containing a personalized link to a secure website where you can fill out and submit your questionnaire. Please note that supplementary questionnaires, such as those for VITAL substudies, are not available online and must continue to be filled out in paper form and returned by postal mail.

Q. I'm planning an active vacation and am trying to pack light. The calendar packs are bulky. Any suggestions as to how to pack my study capsules for my trip?

A. Packing your study capsules while traveling light is possible. Bringing the intact monthly calendar packs with you is best. (Doing so also increases the chance that any travel snapshots that you forward to us will be included in

the “VITAL on the Go” feature of the newsletter!) But here are two other good options. (1) Keeping the “blisters” surrounding the capsules intact, cut the calendar pack into one- or two-week strips containing enough capsules to last for the whole trip. Consider packing an extra strip or two in case of delays. (2) Punch out no more than a one-month's supply of study capsules to keep in a tightly closed bottle or in a pill box along with any other daily medications. (If your trip will be longer than one month, pack some blister strips or intact calendar packs and transfer the capsules to the bottle when your first month's supply runs out. The calendar packaging and outside aluminum pouch work together to ensure that the capsules are protected from heat, moisture, and sunlight, which is why we advise against punching out the capsules more than one month prior to use.)

Q. I am aware that all dietary supplements, including vitamin

D and omega-3 fatty acids, have possible benefits and possible risks. Are the data monitored regularly to be sure that participants are not experiencing undue risks from participating in the study?

A. Vitamin D and omega-3 fatty acid supplements, in the doses that VITAL is testing, are among the safest of dietary supplements. Participant safety is of the highest priority to VITAL investigators. Indeed, in clinical trials, keeping a close eye on all health outcome data to check for safety concerns is required by the National Institutes of Health. Please know that all health outcome data collected in VITAL are carefully reviewed at least once per year by a panel of outside medical and statistical experts who are not affiliated with the study. This panel is called the Data and Safety Monitoring Board. If an unacceptably high risk for vitamin D or fish oil were to be found, that part of the trial would be stopped and participants would be notified as soon as possible.

— DIRECTORS' LETTER continued from page 1

women aged 60-84 years have been assigned to take vitamin D (in a dose equivalent to 2000 IU/day [which is the dose also being tested in VITAL]) or placebo for 5 years. Because D-Health began after VITAL did, its findings likely won't be available for several years after VITAL is completed. (A third large vitamin D trial—the Vitamin D and Longevity Study [ViDAL] in the United Kingdom—is in the planning phase.) With respect to omega-3 fatty acid (fish oil) supplements, VITAL continues to be the only large trial of this

nutrient in a generally healthy population in the world. A few large trials of fish oil in people at high risk of heart disease have been conducted, with promising but inconclusive results (see Issues 2 and 4 of this newsletter, available at www.vitalstudy.org).

We are grateful for your continuing support of VITAL. As always, if you have questions or comments about any aspect of the study, please feel free to contact us at 1-800-388-3963, vitalstudy@partners.org, or the postal address on page 3. Thank you!

Spotlight on VITAL Substudies

As you know, the main goal of VITAL is to determine whether vitamin D and omega-3 fatty acid supplements can prevent cancer, heart attacks, and stroke. However, numerous substudies are focusing on the effect of these supplements on other health outcomes. We very much appreciate the collaboration of VITAL participants in these important substudies, two of which are highlighted here. (*Note:* VITAL participants who qualify for certain substudies on the basis of their medical history receive separate invitational letters to join those substudies. Substudy participation is *optional* and does not affect participation in the main trial.)

Respiratory health

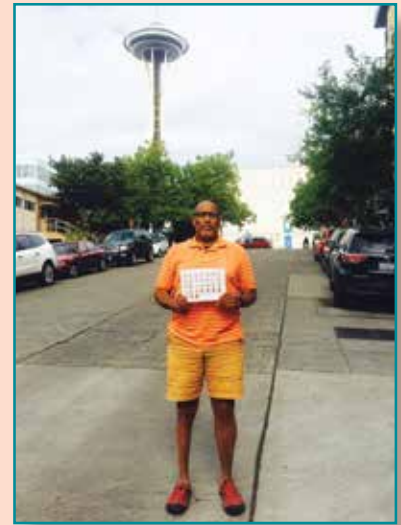
Many people in the United States suffer from chronic respiratory diseases, such as asthma and chronic obstructive lung disease (COPD for short, includes emphysema and chronic bronchitis), or experience bouts of pneumonia (lung infections). To test whether or not vitamin D or omega-3 fatty acids improve flare-ups of asthma or COPD and reduce the risk of developing pneumonia, and to evaluate whether these supplements improve lung function and reduce airflow obstruction, the VITAL team is partnering with Dr. Diane Gold at Harvard Medical School. VITAL participants are asked on annual questionnaires whether or not they had pneumonia in the last year. About 4,300 participants also receive additional questionnaires asking about their respiratory health, including flare-ups of chest or lung problems; antibiotic or steroid treatment for such flare-ups;

shortness of breath; asthma; and asthma control. Nearly 2,000 participants in 11 U.S. locations also received lung function tests (spirometry) at the start of VITAL and again two years later. This research is funded by the National Heart, Lung, and Blood Institute.

Atrial fibrillation

Atrial fibrillation (AFib for short) is an irregular heartbeat 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 lead to stroke or heart failure. AFib is the most common heart rhythm problem in adults aged 65 and older.

VITAL investigators are collaborating with Dr. Christine Albert at Harvard Medical School to determine whether vitamin D or omega-3 fatty acids can prevent the development of AFib. VITAL participants are asked on annual questionnaires whether they have been diagnosed with AFib, and those that report this diagnosis are asked to complete a supplemental questionnaire regarding symptoms, cardiac tests received, related medical conditions, family history, and medications. We also ask participants to sign a medical record release form to allow us to obtain copies of the relevant diagnostic tests and reports from the clinic or hospital where treatment was provided so that we can learn as much as possible about their AFib. The National Heart, Lung, and Blood Institute is funding this research.



Albion L., of New York, in front of the Space Needle in Seattle, Washington



Cora L., of Massachusetts, in the Caribbean Sea, June 2015



**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

Website: www.vitalstudy.org

Preventing Memory Loss

Memory loss is such a frightening and frustrating aspect of aging that of course we want to do what we can to keep our minds sharp. Although genetic factors—which we cannot control—affect a person’s susceptibility to cognitive decline, scientific research conducted over the last three decades has begun to identify strategies that may help to reduce our risk. That said, it is important to recognize that cognitive research is still in a state of relative infancy—that is, there are many small studies with non-rigorous study designs but fewer large, long-term observational studies and even fewer large clinical trials. (Vitamin D and particularly omega-3 fatty acids have shown promise in observational studies but have not been adequately tested in large trials. To help fill this knowledge gap, a VITAL substudy is examining whether these supplements can prevent cognitive decline in 3,000 VITAL participants aged 65 and older.)

Although large clinical trials are necessary to confirm some of these recommendations, here are some strategies currently endorsed by the Alzheimer’s Association* that may help to lower the risk of cognitive decline and dementia. As you look through the list, you may notice that many of the recommendations echo those for good heart health—and that’s no coincidence. The concept of “what’s good for the heart is also good for the brain” emerged early on and has been consistently supported by cognitive research.

■ **Make moderate-intensity physical activity** such as walking, biking, housecleaning, and gardening, or more vigorous activity such as jogging and hiking, a habit. Aim for

150 minutes per week of moderate activity or 75 minutes per week of vigorous activity. In one long-term study of 18,000 female nurses aged 70-81 years, women who were the most physically active appeared to shave 3 years off their cognitive age compared with physically inactive women.

■ **Eat a healthy diet** that *emphasizes* vegetables, fresh fruits, and whole grains; *includes* fish, beans, nuts, poultry, low-fat dairy products, and oils rich in unsaturated fats (such as canola or olive oil); and *limits* sweets, sugary beverages, and red meats. Well-known examples of this dietary pattern are the Mediterranean and the DASH diets.

■ **Engage in cognitively stimulating or challenging activities** such as reading; playing strategy games such as bridge, chess, and Scrabble; memorizing poetry, geographical facts (for example, state capitals), or the like; solving crossword or jigsaw puzzles; learning a foreign language; practicing a musical instrument; trying new recipes; or taking classes at a local college or community center. In an eye-opening randomized trial among 2,832 older adults, those who received as few as ten 60- to 75-minute sessions of mental training not only experienced immediate improvement in their cognitive functioning in daily activities but also continued to show benefits 10 years later, compared with control subjects.

■ **Don’t smoke.** People who have never smoked or who have quit smoking appear to be 30% less likely to experience cognitive decline than current smokers.

■ **Avoid head injuries.** Wear a seat belt when in the car, use a helmet when on a bike, and take precautions to prevent falls, such as doing balance and coordination exercises (for example, yoga or tai chi) and making sure that your home is well lit and free of stumble-inducing obstacles. Nightlights or bedside flashlights are useful for middle-of-the-night trips to the bathroom.

■ **Take care of your mental health.** Seek treatment for symptoms of depression or anxiety, and try to reduce stress. Stress triggers our adrenal glands to release cortisol, a stress hormone that, at chronically high levels, negatively affects the brain.

■ **Get a good night’s sleep.** Seek treatment for conditions that interfere with quality sleep, such as insomnia or sleep apnea.

■ **Avoid or manage medical conditions that raise risk of cardiovascular disease**, including diabetes and the metabolic syndrome, a cluster of symptoms that includes abdominal obesity (belly fat), high triglycerides, high blood pressure, high blood sugar, and low HDL (“good”) cholesterol.

■ **Maintain strong social connections** to family and friends. Although cognitive researchers disagree on the importance of this strategy, some data suggest that people who are socially engaged may be less likely to experience cognitive decline than those who are socially isolated. This may be in part because isolated individuals have fewer opportunities for cognitively stimulating conversations or activities.

*Alzheimer’s Association. Lifestyle changes help reduce risk of cognitive decline, June 1, 2015. Available at http://www.alz.org/news_and_events_lifestyle_changes_help_reduce_risk.asp.