



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

Baseline data offer a glimpse of VITAL study participants

Divided about evenly between men and women. A wide range in age. Racially, ethnically, and geographically diverse. Few current smokers. Many walkers. And, of course, committed to disease prevention research.

That's the picture of VITAL study participants that emerges from a look at the information provided on the initial study questionnaires, as well as feedback from participants during conversations and other correspondence with study staff. There will, of course, be no results available until the end of the study on the main questions concerning the effects of vitamin D and omega-3 fatty acids (fish oil) on cancer, heart disease, and stroke. But the questionnaires

women. Participants are drawn from a range of age and racial/ethnic groups. Fifteen percent of participants are in their 50s, 55% are in their 60s, 25% are in their 70s, and 5% are 80 or older. The oldest participant is 100! With respect to race/ethnicity, 74% of the participants are non-Hispanic white, 20% are black, 4% Hispanic, 1% Asian or Pacific Islander, and 1% Native American. One percent reported more than one race/ethnicity.

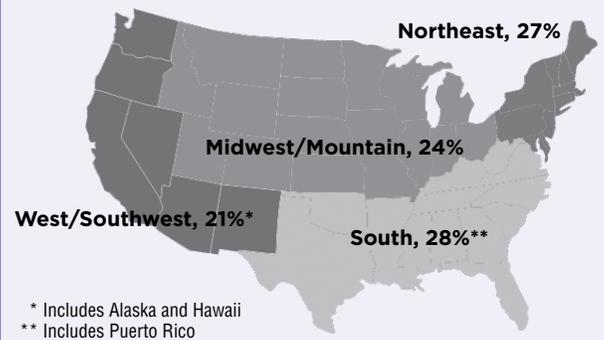
Geographically, the study is well represented throughout the country, with participants residing in all 50

states, the District of Columbia, and Puerto Rico!

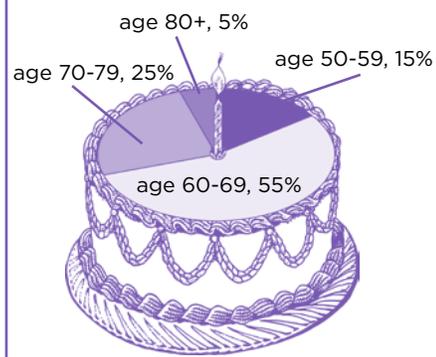
Only 4% of participants are current smokers. More than half of participants have never smoked, and 41% have quit.

— continued on page 4

Participants' Residence (all 50 states!)



Age of Participants



completed at the start of the study provide interesting information on the characteristics of the VITAL study population.

Of the 25,689 participants enrolled to date, 49% are men and 51% are

From the VITAL Study Directors

Dear VITAL participant,

Thank you so much for your continuing dedication to the *VITamin D and Omega-3 Trial (VITAL)*. Your participation in the study will allow us to determine whether these supplements lower the risk for cancer, heart disease, stroke, and other conditions. We are happy to report that more than 25,000 men and women throughout the U.S. have joined the study to date. The front-page article of this newsletter provides a look at the characteristics of your fellow study participants. Thank you again for your commitment to VITAL!



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VITAL Q&A

Q. My doctor wants to know what study pills I am taking as part of VITAL. What should I tell her?

A. Please tell your doctor that you are taking part in a 5-year randomized clinical trial of vitamin D (2000 IU per day) and fish oil (1 gram per day) for the prevention of cancer and cardiovascular disease. Your small study capsules contain **either** 2000 IU of vitamin D **or** placebo, and your large study capsules contain **either** 1 gram of fish oil **or** placebo. At the end of the trial, you will be told which type of study capsules you were taking. Although it may be helpful for your doctor to be aware of your participation in VITAL, neither you nor your doctor should assume that the study capsules can replace any of your prescribed medications.

Q. A recent report linked fish oil to an increased risk for prostate cancer. Should I be concerned?

A. A study published in the August 7, 2013 issue of the *Journal of the National Cancer Institute* found that men with high blood levels of omega-3 fatty acids, which are found in fish and fish oil supplements, were more likely to develop prostate cancer than men with low blood levels of omega-3 fatty acids. However, an important limitation of this study is that the men themselves chose to take fish oil or not. It is likely that many of the men were taking fish oil to treat health issues that put them at higher risk for prostate cancer in the first place. It is also likely that the men taking fish oil were having prostate cancer screening more frequently, such that their cancers were more

likely to be detected than cancers among men not on fish oil. Results from this type of study—called an observational study—are less reliable than results from large randomized clinical trials in which researchers randomly assign one group of men to fish oil and another similar group of men to placebo and follow them over time to see whether one group is more or less likely to develop prostate cancer.

Although this one observational study reported an adverse finding, the relationship between fish oil and prostate cancer actually remains unclear, with past observational studies reporting favorable, unfavorable, and neutral results (see the next Q&A for an example of an observational study that found no association between fish oil and prostate cancer). There are no data from large randomized trials on the relation between fish oil and risk for prostate cancer.

With respect to total cancer, data from observational studies and the few large randomized trials that have been completed to date do not indicate that fish oil increases the risk for this outcome. Also, many observational studies have reported favorable effects of fish and fish oil on the risk of heart attack and stroke. However, additional large trials of fish oil in relation to total cancer, specific types of cancer, and cardiovascular disease are needed, which is why we are conducting VITAL. We expect—as do the National Cancer Institute and the National Heart, Lung, and Blood Institute, the government agencies that are the main sponsors of VITAL—that the benefits of fish

oil will outweigh any risks at the moderate dose (1 gram per day) that we are testing.

It may reassure you to know that all health outcome data collected in VITAL are reviewed at least once per year by a panel of independent medical and statistical experts. If an unacceptably high risk for either fish oil or vitamin D were to be found, that part of the trial would be stopped and participants would be notified as soon as possible.

Q. I heard about another study also called VITAL. Please explain.

A. There is a Seattle-based study called the **VITamins And Lifestyle (VITAL) Study** that is unrelated to our Boston-based **VITamin D and Omega-3 Trial (VITAL)**. The other VITAL is a long-running **observational** study of dietary supplements, including fish oil, in relation to cancer risk among residents of western Washington State. Findings from the other VITAL regarding fish oil and specific cancers have generally been favorable or neutral. In that study, participants who chose to take fish oil were less likely to develop breast and colorectal cancers; about equally likely to develop prostate, lung, bladder, and blood cancers; and more likely to develop endometrial cancer than those who did not choose to take fish oil. However, as explained in the Q&A above, observational studies do not provide conclusive results. Randomized clinical trials such as our VITAL are needed for a clear answer as to whether fish oil lowers, raises, or has no effect on the risk for cancer and other diseases.

Use of Medicare claims data in VITAL

As you may know, Medicare (more formally, the Centers for Medicare and Medicaid Services) routinely collects information about Medicare-funded medical care received by U.S. citizens aged 65 or older. To increase the completeness of the information that we collect on study questionnaires about your health, the VITAL team plans to request information from Medicare related to the health outcomes followed in VITAL and its ancillary studies. Information to be requested from Medicare includes medical diagnoses from hospitalizations, emergency room visits, and outpatient visits, as well as the names of tests, procedures, and prescriptions funded by Medicare. Please note that the information from Medicare does **not** include test

results or actual medical records from doctors' offices and hospitals. If we wish to obtain and review test results or medical records from doctors' offices and hospitals for study purposes, we will always contact you directly to request your permission, just as we do when you report a new diagnosis on your study questionnaires.

The information from Medicare will add to the information that you provide on study questionnaires regarding new medical diagnoses and treatments received during the course of the study. The combined information will enhance our ability to understand the effects of vitamin D and fish oil on many important health outcomes such as cancer, heart disease, stroke, diabetes, and chronic lung disease. Many large studies regularly use Medicare data

to supplement information on study health outcomes.

To obtain your information from Medicare, we will identify you in the Medicare database using your date of birth and, if you provided it, your social security number. We will not obtain or use your Medicare beneficiary ID number. **As always, we are committed to protecting your privacy. We will not share any other information that you provide to us with Medicare, and all data obtained from Medicare will be held strictly confidential and used only for VITAL study purposes.**

If you have questions about—or wish to be excluded from—this part of the VITAL study, please write to us at the address in the box on page 4. Of course, you will still remain a valued participant in VITAL!

VITAL research assistants

Participants, here are the faces connected to some of the voices of the research staff who have been answering your questions and returning your calls. The staff have varied backgrounds and experience, but they all agree that talking directly to participants is the most enjoyable part of their jobs.



Sandra



Alison



Megan

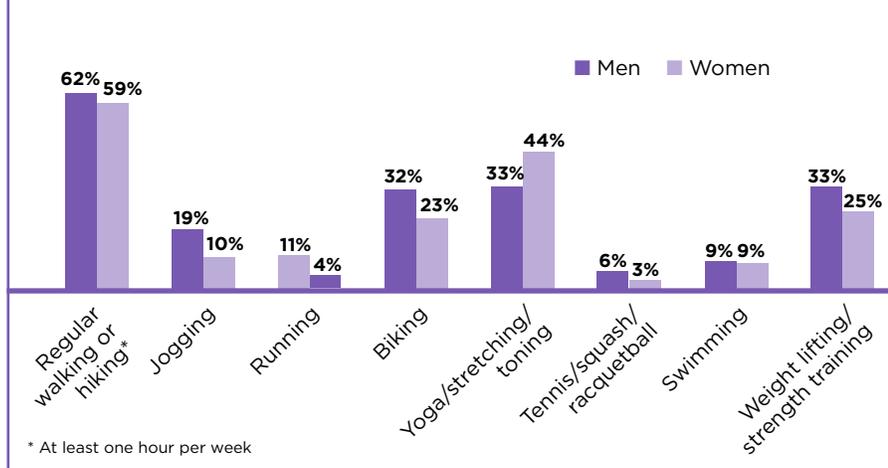


Victoria



Casey

Leisure-time Physical Activity of Male and Female Participants



Walking is by far the most common recreational physical activity reported by both male and female study participants. On average, men walk 135 minutes per week, compared with 126 minutes per week for women. About 1 in 3 men report that their usual walking pace is brisk or very brisk (3 or more miles per hour), compared with about 1 in 4 women. Men report climbing a greater number of flights of stairs per day (an average of 6.1 flights) than women (4.5 flights). Male participants are more likely to jog; run; bike; play racquet sports; and lift weights than female participants, while women are more likely to do yoga, stretching, or toning than men. Both sexes are equally likely to swim.

Although sex differences in patterns of physical activity are pronounced, geographic differences are less so. The only physical activity variable that varied by geographic region was number of flights of stairs climbed daily, with people in the Northeast logging significantly more flights (an average of 7.3 flights) than people in the West/Southwest (3.8) or in the South (3.7), and people in the Midwest/Mountain region climbing an intermediate number (6.2).

At study entry, 13% of participants had a history of diabetes, 53% had a history of high blood pressure, and 37% currently took cholesterol-lowering medications. With respect to cancer screening procedures in the 10 years prior to study entry, 73% of participants reported having had a colonoscopy, 89% of female participants reported a mammogram, and 69% of male participants reported a prostate-specific antigen (PSA) blood test. (For current screening guidelines, please see Issue 2 of the newsletter, available at www.vitalstudy.org.) In addition, 64% of participants reported having had an eye exam within the past year, and another 24% had had one within the past 3 years.

Although the study questionnaires did not ask participants to identify their reasons for joining VITAL, many participants have told us that they wanted to contribute to understanding ways to prevent cancer, heart disease, and stroke. We are interested to learn what motivated you to join the study. Please let us know by writing to vitalstudy@partners.org or the postal address listed to the right (and feel free to include a photo of you with your pill pack). A sampling of responses will be included in a future newsletter.

VITAL on the Go



▲ Sharon L. and Gary R., both of North Carolina, were on a medical and construction mission trip to serve Haitians in the Dominican Republic and discovered that they are both VITAL participants. The photo was taken at a ministry in Puerto Plata, Dominican Republic.



▲ Mai G. of New York, at Camden Yards baseball stadium in Baltimore, Maryland. Number 33 is the retired number of Oriole Hall of Famer "Steady Eddie" Murray.



▲ H. James S. of Washington, at the pedestrian Peace Bridge across the River Foyle in Derry, Northern Ireland.



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