

Clinical trials for breast cancer span the spectrum at Fletcher Allen

Health Care

Written by Sally Pollak Free Press Staff Writer

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Can Vitamin D lower your risk for breast cancer? Will exercise minimize recurrence? Clinical trials are seeking answers.



Dr. Kim Dittus, right, talks with breast cancer patient Joyce Wilson at the Fletcher Allen Health Care Center. / MADDIE MCGARVEY/FREE PRESS

Clinical trials, health tips, and screening advice:

To learn more about the Vitamin D clinical trial, including enrollment information, contact Jennifer Holmes, clinical research

[✉](#) coordinator at the Vermont Cancer Center, at 847-3453 or jennifer.holmes@vtmednet.org
To learn more about the weight loss intervention, contact Karen Wilson, clinical research supervisor at the Vermont Cancer Center, at 656-4101 or karen.m.wilson@uvm.edu

Health tips:

Exercise on a regular basis, aiming for 150 minutes a

week (30 minutes, 5 days a week)

Maintain a healthy weight

Eat a minimally processed, plant-based diet

Have breast self-awareness: know how your breasts feel and look; call a doctor if you feel or notice a change

Source: Kim Dittus, FAHC oncologist

Screening advice:

At or before age 40, discuss your breast cancer risk factors with your physician to determine if you are average, moderate or high risk for breast cancer; this information will be used to determine when to start mammograms, the interval at which you should be screened, and the potential need for other screening techniques, such as MRI imaging

Source: Marie Wood, FAHC deputy director oncology/hematology

Clinical trials related to breast cancer (and other cancers) are important and necessary to help physicians best understand how to treat patients, said Marie Wood, an oncologist and professor of medicine at the University of Vermont College

[✉](#) of Medicine.

Wood is the deputy director of the oncology/hematology division at Fletcher Allen Health Care. She sees patients and conducts research; her interests include women at high risk for breast cancer and cancers with a familial, or genetic, component.

To illustrate the importance of clinical trials, she points to two major advances in breast cancer treatment that became the standard of care and whose effectiveness was proven through clinical trials:

1. Surgery to remove the malignancy and conserve the breast, as opposed to removal of the breast in the surgery known as mastectomy. Through removal of the tumor (and not the breast), patients undergo less drastic surgery.
2. Sentinel node biopsy, advanced by UVM surgeon David Krag, to help determine the stage and extent of the disease using a minimally invasive procedure. The sentinel lymph node indicates if cancer cells have (or have not) spread; removal of fewer lymph nodes is less likely to cause harmful side effects.

"It's important to help people understand that clinical trials are not experiments," Wood said. "They are based in fact and research. Clinical trials are the best care."

At FAHC, there is a spectrum of clinical trials related to breast cancer — targeting everything from prevention to advanced disease, Wood said. "Every cadre that might come in the door, whether it's something we designed ourselves, a national study or industry-sponsored, we offer all these trials," she said.

Researchers who design

and conduct a clinical trial are "challenging the standard," she said. "You have to prove it," Wood said. Through challenging the standard — conceiving of treatments and designing methods to test them — the clinical practice of medicine is advanced, she said.

Testing vitamin D and prevention

Wood is involved in several trials, including one in which she serves as principal investigator in an effort to determine if vitamin D is effective in preventing breast cancer.

The trial involves randomly assigning women to a daily dose of vitamin D (2000 IU) or a placebo. "We're seeing if we can get a clue into Vitamin D and how it might be related to prevention," she said. "You want to make sure that before you open up a big trial and treat a lot of people for a long period of time, that you're moving forward with the right medication or agent."

The researchers will make determinations about the effectiveness of Vitamin D in preventing breast cancer by analyzing several "biomarkers," Wood said. These are indicators of breast cancer risk, as cholesterol can be an indicator of cardiovascular disease.

Noting the "national brouhaha" about Vitamin D deficiency and its possible relation to various illnesses — including mental health disorders, cancers and heart disease — she thought to investigate Vitamin D in relation to breast cancer. The long dark Vermont winters figured into her thinking too, Wood said. (Sunlight increases Vitamin D levels).

"There's been a regional and national focus on Vitamin D and breast cancer risk and recurrence," Wood said, adding that low levels of Vitamin D are associated with a higher risk for breast cancer. But, she said, it has yet to be proven that raising the level will lower the risk. "This study will give us added proof to do a bigger study."

The trial, which started in October 2010, will come to include 250 women at approximately 125 sites across the country, including Burlington. Enrollment is open for this study (see box). Participants need to be pre-menopausal and age 55 or younger. They will be randomly assigned to take a placebo or a Vitamin D supplement each day.

Weight loss and breast cancer recurrence

Kim Dittus, an oncologist at FAHC, has a PhD in nutrition and is an avid exerciser. Her interest in breast cancer research is built around these lifestyle factors.

Dittus recently ran a six-month weight loss study/intervention for women who have completed their breast cancer treatments. Enrollment is underway for a second study, which will be conducted at UVM, UMass, and Dartmouth. (See box). Eligible participants must have completed their treatments no less than two months ago, and no more than one year ago, Dittus said.

The intent of the study is to determine the effect of weight loss and exercise on breast cancer recurrence. Researchers measure certain biomarkers before and after the six-month intervention. These are: inflammation, estrogen metabolism and insulin resistance.

“All three are key factors likely to play a role in breast cancer recurrence,” Dittus said.

Dittus, 50, is a staunch and strong advocate for exercise and weight control as a vital part of women's therapeutic routine. Medications are saving

lives, she said. "Sometimes it feels like lifestyle stuff falls to the bottom," Dittus said.

At age 42, Dittus was diagnosed with early breast cancer. She had surgery and radiation, and took tamoxifen — a medication used in breast cancer treatment.

During her radiation, Dittus trained for a sprint triathlon, a competition with shorter distances in the three events: running, swimming, and cycling. Dittus recognizes that her mindset about her diagnosis was significantly different than that of the majority of her patients. This is because she knew, through her medical training and experience, that the diagnosis was not a threat to her life.

“It’s just a heavy diagnosis,” she said, noting the impact of body-image issues. “I think it’s really hard for women to think that even an early cancer won’t impact her life.”

Data

has yet to be analyzed for the first run of Dittus’ weight loss study. It started with 74 women, about 30 percent of whom did not complete the trial, Dittus said.

The study called for participants to exercise 300 minutes a week, and no one achieved that measure, she said. On average, they added 15 minutes of exercise per day to their baseline level. Calorie intake was designed on an individual basis, and participants lost an average of 6.7 percent of their weight, Dittus said.

For the new multi-site study, researchers will modify the way in which they monitor and measure the exercise component, Dittus said. The previous study used a device

called an accelerometer, which records the movement of the person wearing it. This will be supplemented with a pedometer, which measures steps taken.

With the pedometer, there will be more day-to-day feedback on exercise, Dittus said. In addition, there will be greater discussion of the exercise component of the study.

“One of the biggest predictors of long-term weight loss success

is exercise,” she said.

The after effects of cancer treatment that Dittus is concerned with helping her patients with include:

Peripheral numbness and tingling

Memory difficulty and other cognitive symptoms, commonly known as "chemo brain"

Range of motion challenges

Weight gain

Loss of muscle mass

Fatigue

"We are very fortunate to have these problems, the cancer-survivor problems," Dittus said. "We are saving lives and people are living so much longer after cancer."

Exercise is the most valuable intervention for these problems, Dittus said.

"The thing about exercise, and to some extent nutrition, it impacts all those things," she said.

The value and benefit of exercise extends to patients who are able to exercise in some fashion during chemotherapy, Dittus said. If a breast cancer patient has the energy to get up and take a walk, of whatever duration, Dittus encourages her to do that.

"It's a challenge," Dittus said. "Going through chemotherapy can be daunting. It's a lot of hard work. I truly believe that those people who can exercise during chemotherapy do better and there is research to back it up. But it's not going to be an easy task."

Who participates in clinical trials?

Enrolling patients in a study is a complicated endeavor, one that requires caution, Wood said. She presents an overview of the trial and arranges for the patient to meet with a data manager who can go over the "nuts and bolts" of the investigation.

"I think sometimes people are afraid of disappointing their physician," she said. "I try to talk about it in a very balanced way."

Communication between physicians and patients has moved from a "paternalistic" relationship to one characterized by greater dialogue, Wood said.

A physician should make sure her patient has all the available information and allow the patient to make the decision "thinking it's in their best interest."

That said, there are situations when Wood says to her patient: "You know what, I think you need to do this trial."

Dittus and physician Patti O'Brien, colleagues of Wood, say patients who enroll in clinical trials are typically motivated by their desire to give back, and their hope that subsequent patients will benefit from the science.

"Everybody wants to pass it along," O'Brien said. "The vast majority really want to participate because they want to make it better for the next person to go through with it."

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