

ARE YOU ELIGIBLE?

You may be eligible to participate in this study if you have been taking an Aromatase Inhibitor for breast cancer for at least six months. We will ask you some questions by phone to make sure you are eligible for the study before we meet in person.

HOW WILL YOU BENEFIT?

By participating in this study, you will play an important role in finding out how exercise may affect the side effects of an important treatment for breast cancer. You will learn how to exercise safely and how to make exercise an enjoyable part of your life. It is only through the generous cooperation of people like yourself that we can learn more about treatment for breast cancer.



Photo includes Principal Investigator, exercise trainers, health counselors, project director and research associates.

WHO ARE WE AND WHO IS PAYING FOR THE STUDY?

The Hormones and Physical Exercise (HOPE) Study, a Yale School of Public Health study, has been funded by the National Institutes of Health. The principal investigator is Melinda Irwin, PhD, MPH (melinda.irwin@yale.edu or 203-764-8427), Associate Professor in the Yale School of Public Health.

NEED MORE DETAILS?

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HOPE

Hormones & Physical Exercise



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We are inviting women who have been treated for breast cancer to participate in the Hormones and Physical Exercise (HOPE) Study. This research study will examine if a regular program of moderate-intensity exercise improves side effects from Aromatase Inhibitors (e.g., Arimidex, Femara, or Aromasin), a drug taken by many postmenopausal women who have had breast cancer. Half the women in the study will be chosen at random to start an exercise program for twelve months. The other half will participate in a health education program for twelve months.

The exercise program will be individually tailored to your needs, but will include two strength training sessions per week at a gym and 150 minutes per week of aerobic exercise, such as brisk walking (e.g., three sessions for 50 minutes each or five sessions for 30 minutes each; two of the sessions can be done at the gym before or after the strength training). A certified exercise trainer will meet you at the gym to monitor your exercise program, motivate you to safely increase your exercise, and educate you on the benefits of exercise. A twelve-month local health club membership will be provided to those in the exercise group.

The health education program will involve a health counselor telephoning you once a month to discuss topics of interest for women who have had breast cancer. Upon completion of the twelve-month program, an exercise trainer will also develop a personalized exercise program for you.

WHY YOU SHOULD PARTICIPATE IN THE STUDY?

We know that women who have side effects from Aromatase Inhibitors are more likely to stop taking this important medication. We want to find out if exercise might help lessen these side effects and help women keep taking this medication.

WHAT DOES THE STUDY INVOLVE?

A total of 180 women will be enrolled in the study. You cannot choose whether you are in the exercise program or health education program; a computer program will randomly (like flipping a coin) select 90 women for each group. The study involves a series of visits to our New Haven facilities (2 at the beginning of the study, 1 in the middle of the study and 2 at the end of the study) as well as an initial visit, which can be at your home or at our New Haven office. All 180 women will complete health and medical history questionnaires. During your visits to our facilities, we will draw blood from your arm and have you complete a DEXA bone density scan. The DEXA scan involves lying still for about 10 minutes on a padded table. The test does not require you to undress. In addition, we will have you do a treadmill exercise test at the beginning and end of the study (you do not need to be fit or know how to walk on a treadmill to do the test, we will instruct you on how to do the test). All these tests are performed by trained staff. For privacy purposes, all information collected is labeled with a study ID number and not your name. All questionnaires, the blood draw, and DEXA scan will be administered at the beginning, middle, and end of the study. The treadmill exercise test will be administered at the beginning and end of the study. If in the exercise group, our exercise trainer will meet you at the gym each week of the twelve-month study. If in the health education group, our health counselor will call you monthly (at your preferred day and

time) to discuss health issues of interest for women who have had breast cancer. These calls will last approximately 15 minutes.

WHAT DO WE MEAN BY “EXERCISE PROGRAM”?

The exercise goal involves two strength training sessions each week and 150 minutes per week of physical activity, such as brisk walking, for twelve months. A certified exercise trainer will work closely and individually with those in the exercise group throughout the twelve months to help women gradually improve their ability to exercise.

WHAT DO WE MEAN BY THE “HEALTH EDUCATION PROGRAM”?

If you are placed in the health education program you would simply go about your usual care activities and follow your doctor’s recommendations. However, a health counselor would also call you monthly to discuss topics of interest for women who have had breast cancer. At the end of the twelve-month study, a certified exercise trainer will also develop a personalized exercise program for you.

HOW LONG WILL THE STUDY LAST?

The study will last twelve months.

WILL YOU BE ASKED TO CHANGE YOUR DIET?

No, in fact we are interested in examining the effects of only exercise on side effects of Aromatase Inhibitors.

ARE THERE ANY COSTS TO PARTICIPATE?

No. All testing and telephone sessions are provided to you at no charge. Also, for any visits to our office, we will pay for your parking and provide you with a \$20 gas card. If you complete the twelve-month study and come for the six-month study visit, we will also give you a \$50 gift certificate to Walmart.