

UC San Diego Researcher Awarded \$5.3 Million for Breast Cancer Survivorship Study

Moores UCSD Cancer Center will lead clinical trial consortium involving five leading NCI-Designated Cancer Centers

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The University of California, San Diego School of Medicine has received a \$5.3 million grant from the National Cancer Institute to conduct and lead a first-of-its-kind, four-year clinical trial to show the effects of weight loss and increased physical activity on quality of life and on co-existing medical conditions in overweight breast cancer survivors. This trial is designed as a vanguard component of a larger study that will examine the effect of weight loss on recurrence risk for breast cancer survivors.

Cheryl Rock, PhD, RD, professor of Family and Preventive Medicine at the UCSD School of Medicine, will lead a multi-disciplinary team of experts representing five leading NCI-designated Comprehensive Cancer Centers - including the Moores UCSD Cancer Center - in this trial, also known as the ENERGY (Exercise and Nutrition to Enhance Recovery and Good Health for You) study.

"Excess body fat is a major adverse prognostic factor for women with both pre- and postmenopausal breast cancer," said Rock. "Up to 30 percent of breast cancer survivors experience anxiety or depression that persists after the completion of treatment. We believe weight loss and increased physical activity in overweight breast cancer survivors will have a positive effect on psychosocial problems and co-existing medical conditions, and may possibly reduce the risk of breast cancer recurrence."

Combining the investigators' experience in diet and exercise, cancer survivorship, nutritional epidemiology, breast oncology trials and breast cancer outcomes research, the team will conduct a randomized, controlled study that will track and measure improvements in quality of life and co-existing medical conditions in 800 overweight or obese breast cancer survivors.

Participants must be at least 21 years old and have been diagnosed with stage I, II, or IIIA breast cancer. They will be involved in a two-year active intervention program.

The weight-loss intervention uses a cognitive-behavioral group-based program, telephone counseling and home-based support that has been developed and tested in previous successful studies conducted by the ENERGY study's investigators.

"There are various goals of the ENERGY study," Rock said. "First, we are aiming for weight loss and maintenance among all 800 subjects, with a primary hypothesis that they will achieve an average weight reduction of at least seven percent of initial weight. We're also assessing the impact of the intervention on their quality of life, particularly physical functioning and fatigue." She added that the researchers will also conduct a cost-effectiveness analysis that includes an assessment of the impact of the intervention on medical co-existing conditions.

The investigators have strategically designed the ENERGY study to lead to an expanded full trial of 2,500 women. If the eventual full trial can document lower breast cancer recurrence risk, it would provide evidence to support weight loss management for breast cancer survivors as a new standard of clinical care.

"The ENERGY Study has great potential to have a major impact on clinical management and outcomes after a diagnosis of breast cancer," Rock said. "If the improvements in psychosocial and medical co-morbidities that we expect to find can be documented in this trial, this finding could itself change the norms of clinical practice and set a new aspect of care for breast cancer survivors after initial treatment."

Additional study investigators are Bilge Pakiz, EdD, and Barbara Parker, MD, Moores UCSD Cancer Center; Wendy Demark-Wahnefried, PhD, RD, University of Alabama at Birmingham; Tim Byers, MD, MPH, and James Hill, PhD, University of Colorado; Graham Colditz, MD, DrPH, Washington University in St. Louis; and Patricia Ganz, MD, UCLA.

For additional information about the ENERGY study and to inquire about participation, contact Shoshi Barkai, MS, RD, at Moores UCSD Cancer Center, 858-822-2779.

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