

"Studies have shown that excess body weight is linked to a higher risk of breast cancer recurrence. However, we do not know whether weight loss in women who are overweight or obese when they are diagnosed with breast cancer can reduce the risk of breast cancer recurrence and improve survival.

This study could establish weight loss as a new kind of breast cancer treatment, potentially improving cancer outcomes in hundreds of thousands of women with breast cancer around the world."

-Jennifer Ligibel, MD



The Breast Cancer Weight Loss (BWEL) Study

STUDY TITLE: Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant

Treatment of Overweight and Obese Women With Early Breast Cancer

TRIAL NUMBER: NCT02750826

FOCUS: Treatment

TRIAL PHASE: Phase III (Phase 3)

WHAT HAPPENS IN THIS STUDY?

This study's goal is to test whether weight loss in overweight and obese women with breast cancer will help prevent their cancer from coming back (recurrence).

This is a <u>randomized</u> trial, which means that neither the doctor nor the participant choose the treatment group. Instead, participants will be assigned by chance to a treatment group. They will either receive the study's health education program or the health education program plus a weight loss intervention.

ARE YOU ELIGIBLE?

A woman may be eligible for this study if she has been diagnosed with breast cancer within the last 14 months. The cancer must be <u>early stage (II-III)</u> and <u>HER2-negative</u>. The woman must also be overweight or obese (BMI ≥27) at the time of diagnosis.

The status of this study is subject to change. To see the most up to date information, visit breastcancertrials.org or clinicaltrials.gov.

WHAT WILL THIS MEAN FOR PATIENTS?

Previous studies found women who are overweight or obese at diagnosis have a greater risk of breast cancer coming back compared to women who were thinner at diagnosis. This is the first study designed to test the impact of weight loss on breast cancer recurrence. If this study shows losing weight improves survival rates in breast cancer, it could mean weight loss programs could become a standard part of breast cancer treatment for people living in North America.

WHO DO I CONTACT ABOUT THE BWEL STUDY?

LEAD TRIAL PI AND TRIAL LOCATION:

Jennifer Ligibel, MD Dana-Farber Cancer Institute, Boston, Massachusetts, United States, 1-857-215-2935, BWELStudy@partners.org

OTHER STUDY LOCATIONS:

This study is offered at many sites across the country. See if there is a research site near you.



KOMEN CONNECTION

Jennifer Ligibel, MD, the Principal Investigator of this study, is a Komen Scholar from Dana-Farber Cancer Institute. Her work on this Komen funded trial has already involved over 2,400 women with breast cancer in the U.S. and Canada. Her work is helping people make healthy lifestyle changes. These lifestyle intervention programs have the potential to impact large numbers of cancer survivors.

BREAST CANCER CLINICAL TRIAL INFORMATION HELPLINE

Call our clinical trial information helpline at 1-877 GO KOMEN (1-877-465-6636) or email at clinicaltrialinfo@komen.org to talk with a trained specialist. Our caring and trained staff provide support and education about clinical trials to help people gain a better understanding of clinical trials.

Disclaimer

This information is being provided for education purposes only and does not contain all information related to this clinical study. The study status and eligibility criteria may change. If you are interested in learning if this study is right for you, please reach out to the study coordinator or your doctor for more information.