About The Study

This study will evaluate if prolonged overnight fasting, structured exercise, or a combination of both can reduce fatigue in women with advanced breast cancer who are starting CDK4/6 inhibitor treatment.

Ask your doctor about whether this study is a good fit for you.

www.craneresearchlab.org

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UNIVERSITY OF MIAMI HEALTH SYSTEM

Dana-Farber Cancer Institute

Do you have metastatic breast cancer and are planning to start CDK4/6 inhibitor treatment?

Are you interested in trying an exercise and/or prolonged overnight fasting or education support program designed for women with advanced breast cancer?

Talk to your doctor about:

FastER

A FASTING AND EXERCISE STUDY FOR WOMEN WITH ADVANCED BREAST CANCER

www.craneresearchlab.org

Why Is This Study Being Done?

- The majority of women with advanced breast cancer have hormone receptor positive tumors, and most will start CDK4/6 inhibitor therapy as part of their treatment.
- CDK4/6 therapy is highly effective, but has side effects, including fatigue, which can negatively affect quality of life.
- These side effects may also impact whether patients are able to receive the full, planned dose of their treatment.
- Lifestyle interventions, including exercise and prolonged overnight fasting, have been shown to reduce side effects from treatment and improve physical function and overall quality of life. More research is needed in patients with advanced breast cancer.
- This study will assess the impact of a 12-week program of prolonged overnight fasting, exercise, or a combination of both, on fatigue and other treatment outcomes for women who are receiving CDK4/6 inhibitor therapy.

If You Join This Study, You Will:

Be enrolled in a one-year-long study that will include a 12-week program featuring one of the following:

- Supportive care education
- Prolonged overnight fasting
- Structured exercise program
- Prolonged overnight fasting **plus** structured exercise program

All programs will include regular telephone or video-based visits with a health coach, and exercise programs will include some in-person visits. Visits with the health coach will be scheduled at your convenience.

In addition to the 12-week program, participants will be asked to complete questionnaires and assessments at 12 weeks, 6 months, and one year. All participants will receive a Fitbit device to keep.

You May Be Able To Join This Study If:

- You have been diagnosed with hormone-receptor positive metastatic or locally unresectable breast cancer.
- You are starting endocrine therapy in combination with CDK4/6 inhibitor therapy.
- You do not have diabetes.
- You are not already fasting or exercising consistently.