Clinical trial summary (S2010)

Monitoring Symptoms to Help Women Keep Taking Hormone Therapy for Early-Stage Breast Cancer

What is the purpose of this clinical trial?

Side effects are a common reason women stop taking hormone therapy for breast cancer early. To improve how doctors help women with side effects, this study tests a new way of monitoring symptoms during treatment.

Generally, doctors ask patients about their symptoms at clinic visits every few months. This study tests asking women about their symptoms more often. Researchers want to find out if monitoring symptoms in between clinic visits can improve side effects from hormone therapy for women.

This trial is set up to find out:

- If women are more likely to keep taking hormone therapy when their doctors monitor symptoms in between clinic visits
- If women's side effects improve when their doctors monitor symptoms frequently in between clinic visits

Why is this trial important?

Stopping hormone therapy early increases the chance of breast cancer coming back. Many side effects are treatable, so doctors hope improving how they monitor symptoms will help more women stay on treatment. This trial is a chance to see if more communication between doctors and patients helps them better manage side effects.

Who can be in this trial?

This trial is for women, age 18 and older, with stage 1, 2, or 3 breast cancer.

This trial is for people who:

- Have breast cancer that is hormone receptor-positive
- Started or will start oral hormone therapy for breast cancer
- Can complete surveys in English or Spanish

This trial is not for people who:

- Have cancer that has spread to other places in the body outside of the breast
- Were diagnosed with breast cancer after menopause
- Are planning to be pregnant during the study

What can I expect during the trial?

You receive cancer treatment as usual. You and your doctor choose your hormone therapy.

To determine how your doctor will monitor your symptoms, a computer will randomly assign you to 1 of 2 study groups.

Group 1:

- You have regular visits with your doctor as usual

Group 2:

- You have regular visits with your doctor as usual
- In between visits, you answer short surveys about your symptoms by phone, email, or text message

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.

If your symptoms get worse at any time, always tell your doctor right away.

How long will I be in the trial?

You will be in the study for about 1 year and 8 months. You may choose to stop and leave the study at any time for any reason.

Are there costs to join the trial? Will I get paid?

You will not be paid for being in the study. Using your smartphone or tablet for the study surveys may add costs to your data plan.

Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to **www.ClinicalTrials.gov** and search using the national clinical trial number: **05568472**

Key information

This trial is for adults 18 years or older being

Full trial title: A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence with Endocrine Therapy in Young Women with Stage I-III Breast Cancer (ASPEN)

Protocol number: S2010

NCT number: 05568472

Trial sponsor: SWOG Cancer Research Network

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Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.