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Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

NRG ONCOLOGY

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Visit the patient webpage for this study:

ABOUT THE TRIAL

NRG-CC012CD

In this study, you will get weekly symptom monitoring telephone calls. The purpose of these calls is to assess 24 symptoms. These symptoms can be common during cancer treatment and include fatigue, pain, sleep difficulties, anxiety, digestive, skin, and other problems. Your oncology doctor's office will receive a weekly summary of your symptoms. This study will determine if people on oral anti-cancer treatment who have these symptom monitoring calls plus other support will have less severe symptoms and less visits to the hospital, emergency room or urgent care compared to only symptom monitoring calls. The researchers also want to find out if people in your doctor's office (such as doctors, nurses) find symptom monitoring and other support useful.

There will be a total of 516 people aged 18 or older who take oral anti-cancer treatment in this study. Everyone in this study will get a 30-minute telephone interview at study entry, and 13 and 17 weeks later. All study assessments and support are offered in English or Spanish, based on your language preference.

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org

Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
People who will be starting or have started an oral anti-cancer treatment other than hormonal therapy in the past 4 weeks.

Can I change my mind if I choose to take part in this study?
Yes, because taking part in this study is voluntary. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, you will receive the usual care from your doctor's office. As part of usual care, you can discuss symptoms during doctor's office visits, and you can contact your doctor or nurse by phone or patient portal to get advice on how to relieve symptoms.

What are the possible treatments?
There are two study groups. Your doctor's office will be assigned randomly (by chance) to be in one of the two study groups.

If your doctor's office is in group 1, you will receive your usual care and weekly automated symptom monitoring telephone calls over the 17 weeks. The calls will be at a good time for you and will last about 15 minutes. You can change your preferred time at any point by calling the study office.

If your doctor's office is in group 2, you will receive your usual care and weekly automated symptom monitoring telephone calls over the 17 weeks. The calls will be at a good time for you. Each call will last about 20 minutes. You can change your preferred time at any point by calling the study office. People in group 2 will also get a printed symptom management handbook with ideas to help you manage your symptoms at home. This handbook is available in English or Spanish. You may also get calls from a study counselor for symptoms related to your mood during the first 12 weeks. If you are offered counseling, counseling calls will be about 30 minutes at a good time for you and will be free of charge.

How long will I be in this study?
You will be in the study for 17 weeks.

Are there side effects?
There is a risk you may feel uncomfortable answering some of the questions. You do not have to do any study-related task that feels uncomfortable or upsetting. You have the option of stopping participation at any time during the study or skipping some of the questions or calls. As with any research study, a loss of confidentiality is a possible risk. Researchers have taken steps to make this risk very small.

MORE INFORMATION

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call:
1-(800)-4-CANCER (1-800-422-6237).