Comprehensive Cancer Center Participant Information and Consent for Research Participation Form

Title of Research: Determining the Effectiveness of Patient Navigation in Cancer Care.

Study Sponsor: Montage Health Foundation

IRB Number: 00004326

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Why is this research being done?

Community Hospital's Comprehensive Cancer Center is conducting this research to evaluate whether providing enhanced patient navigation services to cancer patients can help overcome barriers to care ranging from the need for practical support (transportation to and from appointments, health insurance, co-payments, and other financial barriers), to lack of care coordination (falling through the cracks between one doctor or service and another), and improve the distress cancer patients can experience.

Why am I being asked to participate in this study?

Community Hospital's Comprehensive Cancer Center and your doctors are committed to continuously improving the care and services we provide. Studies like this one (that involve actual cancer patients like you), are the best way of determining if a new treatment or service is safe, effective, and work better than the current treatment or service. This form will explain the study to you, so you can make an informed decision about taking part in the study.

How will the study be conducted?

Patients who agree to participate will be randomly assigned (like the flip of a coin), to one of two types of navigation services. Both types of navigation services aim to help provide patients with resources that will meet the care need identified by the patients themselves. The two types of navigation services are:

Control group: Participants assigned by chance to this group will receive a meeting with a member of the navigation service, an information packet, and education on reporting adverse effects of their treatment to their care team, to mitigate the potential for non-study-related adverse events from their medical treatment.

Baseline and follow-up questionnaires and interviews will take place at the start, midway through, and at the end of treatment. The patient navigation team communicates these needs or patient concerns to the patient's treating physician, so that the physician can address the issue, and/or refer the patient for services available through the cancer center.

Study group: Participants assigned by chance to this group will have access to the services provided by a team of trained oncology nurses, social workers/marriage and family therapists, and lay navigators (i.e. patient navigation team). Baseline and follow-up questionnaires and interviews will take place at the start, midway through, and at the end of treatment. The patient navigation team will either addresses the barriers and needs identified, or refer patients to providers to address the identified barriers and needs. The patient navigation team also helps patients navigate through the healthcare system, between the scheduled follow-up questionnaires and interviews.

We anticipate that a total of 84 patients will participate in this research study.

What will I be asked to do?

If you agree to participate in the study:

1. You will be asked to respond to three short surveys; one at the start of your participation, the second one midway through your treatment, and the third at the end of your treatment.
    - **Baseline and follow-up questionnaires and interviews:** At the start of the study, a member of the study team will ask you to complete a survey to assess patients' for distress, quality of life, barriers to care, needs for supportive care, and either addresses the barriers and needs identified, or refers patients to providers to address the identified barriers and needs. The second survey will repeat the questions from the first survey. Asking the same questions before and after your participation helps the researchers determine whether the study has had a benefit to you. The third survey will again ask the same questions, but will also contain questions about your experience with the navigation services to which you were assigned. These questions will help researchers determine how the services may need to be adapted to respond to the needs of the patients.

      The three surveys will be done in-person, or over the phone. The baseline assessment (including study enrollment) takes about 60 minutes to complete, the follow-up surveys will take about 20-30 minutes.

2. Participants assigned by chance to the study group will have frequent check-in sessions with the patient navigation team between scheduled survey appointments, via electronic mediums like phone, email, telehealth visits, and some in-person meetings; continuously identifying needs and barriers to care and linking patients to financial or psychosocial support resources.

How long will I be asked to participate in this study?

The entire study will last 24 months. The duration that it takes each individual participant to complete all study-related tasks, depends on the length of their treatment. Your part in the study will last about two to seven months.

What are the potential risks and discomforts I may experience?

There are no physical risks to you by participating in this study. It's important to note that everyone's cancer experience is unique, and that our goal is to best meet the needs of all cancer patients; which means that some participants may find the surveys to be too personal. While it is important to answer survey questions, you do not have to answer any questions that make you uncomfortable.

Is there a cost to me for participating in this study?

There is no cost to you as a result of participating in this study. You or your insurance companies are responsible for any costs directly involved with your clinical care. Your participation in this study may last up to 60 minutes (for the first session). All other sessions (the nurse visit and 2 follow-up appointments) should last about 20-30 minutes. Participants may incur minor expenses associated with traveling to and from these three appointments.

Will I be paid for my participation in this study?

Participants will be compensated with a $20 gift card once you have completed each part of the study (Enrollment, mid-treatment, and end of treatment) for a total of $60.

Are there any other benefits from participating in this research study?

Taking part in the study may or may not help you. Taking part in this study may help you find resources to help patients overcome barriers to care, and improve their quality of life. By taking part in this study, you will help the study team to determine the type of navigation services that are best suited for current and future patients.

Are there any alternatives to participating in this study?

If you choose not to be in this study, you may continue to receive medical care and services in your doctor's office or our cancer center. You may also discuss alternatives to participating in this study with your health care provider.

How will my personal information be protected?

Community Hospital of the Monterey Peninsula is dedicated to maintaining the privacy of your health information. Release of your health information is limited to the information required to achieve the purpose for which the information is being used or disclosed. According to federal and state law, Community Hospital must follow the privacy practices described in this notice.

- If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. "Personal health information" is health information about you that could identify you, because it includes information such as your name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures.

- All data will be collected for research purposes only. All study forms will be marked with only the participant's initials, medical record number, session number and date. All records will be stored in locked files (physical or on computer) in locked rooms accessible only to research staff. Data collected will be stored on password-protected computers and marked with only the participant's initials, medical record number, session number and date. Data gathered from people who attend the screening but do not meet inclusion criteria or decide not to participate will be stripped of personal identifiers or links and only the reason for study exclusion will be kept.
- Your answers are confidential. The findings of the study may be published, but individual participants will not be identified.

A description of this clinical trial will be available at https://www.chomp.org/services/cancer-center/cancer-center-services/diagnosis-and-treatment/clinical-trials and on http://www.ClinicalTrials.gov. These Web sites will not include information that can identify you. At most, the Web sites will include a summary of the results. You can search these Web sites at any time.

Am I required to participate in this research?

Participation in this study is entirely voluntary and can be discontinued at any time. Declining to participate in the study does not impact a potential participant's healthcare provision.

Who can I call if I have questions?

If you have any questions or should you no longer wish to remain a part of the study, please call the Cancer Center (831) 625-4697.

Comprehensive Cancer Center
Montage Health

Consent to Participate in Research Study

I had the opportunity to ask questions about this research study, and my questions have been answered to my satisfaction. I understand that I can withdraw from this study at any time and contact my health care provider or research team if I have questions.

I will receive a copy of this consent form.

I understand that signing this document indicates that I have read this consent form (or have had it read to me), that my questions have been answered to my satisfaction, and that I voluntarily agree to participate in this research study.

Date	Time	Patient/Surrogate signature
Print Name		Relationship to Patient
Date	Time	Physician signature

Witness Statement

I have verified with the patient or surrogate decision maker that s/he has received sufficient information concerning participation in this research study and that s/he consents to proceed.

Signature: _____ Name: _____
(Signature of witness) *(Print)*

Interpreter's Statement

I have faithfully read the foregoing document to the patient (or the patient's legal representative), _____, in the patient's or legal
(Print name)
representative's primary language _____.
(Print name of language)
S/he understood all of the terms and conditions and acknowledged his/her agreement by signing the document in my presence.

Date: _____Time: _____AM/PM

Signature: _____Name: _____
(Interpreter signature) *(Print)*

Interpreter service vendor or telecommunication service: _____