“Adaptation of Ca-HELP Intervention in Rural Geriatric Cancer Patient Population”

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MAURY REGIONAL MEDICAL CENTER

Informed Consent for Participants
in Research Projects Involving Human Subjects

RESEARCH STUDY: Ca-HELP Intervention in Rural Geriatric Cancer Patient Population

WHAT IS THIS STUDY ABOUT?
The Cancer Health Empowerment for Living without Pain (Ca-HELP) is an evidence-based communication tool that empowers and engages patients to communicate effectively with their physicians about pain. The purpose of this study is to adapt and test the communication tool for use among patients, age 65+, living with cancer in rural communities.

DESCRIPTION OF THE STUDY:
Patients will first provide informed consent. Next, patients will be administered pre-intervention study surveys over the telephone. They will then participate in the intervention in person or over the telephone, depending on the recommended results from completion of Aim 1. Following intervention completion, post-intervention study surveys will be administered over the telephone. Study staff will extract data (e.g., disease stage, etc.) from the electronic health record. After the pre and post-intervention surveys are completed, participation in the research project is complete.

POTENTIAL BENEFITS:
Ca-HELP coaches patients to ask questions, make requests, and signal distress to their physicians in order to achieve improved pain control. Previous research indicates significant improvement among cancer patients in their self-efficacy to communicate about their pain to their oncologists and reductions in pain misconceptions and pain-related impairment. Improving your ability to talk with your doctor about your pain is one potential benefit of the study.

POTENTIAL RISKS:
Participants may find it distressing to think about their pain and/or the idea of speaking to their doctor about their pain. These is also minimal risk from a potential loss of confidentiality, however, this risk will be minimized by carefully protecting your data.

PARTICIPATION:
Participation in this research is voluntary. You have the right to refuse to participate or answer any questions. If you choose not to participate, you will continue to receive care at Maury Regional Medical Center. If you decide to participate, you may change your mind at any time about participating in the study without consequences.

COSTS:

There will be no costs associated with participation in this study.

COMPENSATION:
Phase 2 participants, which includes patients, will be compensated $25.00 for completing pre-intervention assessments and $25.00 for completing post-intervention assessments.

CONFIDENTIALITY:
Study investigators will have access to some medical information of patients who participate in the study. Clinical variables will be collected from medical records and will include the following: cancer diagnosis and stage, treatment received, co-morbid conditions, and Karnofsky performance status. While absolute confidentiality cannot be guaranteed, all research material which could identify you will be kept as confidential as possible within the state and federal laws. If the results of the study are presented in any public forum, you will not personally be identified.

OTHER INFORMATION:
This project has been reviewed and approved by the Institutional Review Board at Maury Regional Medical Center, which reviews and approves projects conducted at the hospital. If you have questions or concerns about your rights, contact Beth Fleming, convener of the hospital Institutional Review Board at 931-381-1111 extension 2264. If you have any questions or concerns about the study, please contact Sue MacArthur at 931- 380-4053.

I have read and understand the Informed Consent and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ Date_____
Participant Signature

Print Last Name: _____ First Name:_____

Witness:_____ Date:_____

IRB approval date: