Cancer Research Consortium of West Michigan
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FAST FACTS

S1912CD - A RANDOMIZED TRIAL ADDRESSING CANCER-RELATED FINANCIAL HARDSHIP THROUGH DELIVERY OF A PROACTIVE FINANCIAL NAVIGATION INTERVENTION (CREDIT)

ELIGIBILITY CRITERIA

1. Disease Related Criteria – Patient
    a. Patients must have a diagnosis of a metastatic solid tumor or a hematologic malignancy and must receive anti-cancer treatment per the timing described in Section 5.2a (i.e. chemotherapy, hormonal therapy, targeted therapy, biologic therapy, immune therapy, bone marrow transplant). Registration must occur within 120 days after diagnosis. Patients with indolent hematologic diseases undergoing observation alone are not eligible.
    b. Patients with recurrent solid tumors will be allowed as long as 1) this is the first presentation of metastatic disease and 2) the diagnosis of the metastasis is at least 180 days (6 months) after the diagnosis date of the previous earlier stage cancer.
    c. Patients with a history of secondary malignancy are allowed as long as they were not diagnosed within the previous 24 months, are not on active therapy, and are disease-free. Patients with adequately treated basal cell or squamous cell skin cancer, and *in situ* cervical cancer at any point prior to enrollment are eligible.
2. Prior/Concurrent Therapy Criteria – Patient
    a. Patients who have started anti-cancer treatment for the current diagnosis must have started within 60 days prior to registration.
    b. Patients who are planning to start anti-cancer treatment for the current diagnosis must start within (≤) 30 days after registration.
    c. Patients are allowed to be co-enrolled on other clinical trials (including non-treatment studies and studies that may or may not include investigational drugs).
    d. Patients may not be enrolled in hospice care at the time of registration.
3. Clinical/Laboratory Criteria – Patient
    a. Patients must be at least 18 years of age.
    b. Patients must have a Zubrod performance status of 0-2.
    c. Patients must complete the baseline PRO questionnaires prior to registration and must be able to complete questionnaires in English or Spanish.
    d. Patients must provide their full name, primary address in the U.S., birth date and social security number at registration for the purposes of accessing credit report data. (This may be obtained directly from the patient, study questionnaires, or the medical record.)
    e. Patients must provide email and telephone number for the purposes of being contacted by financial navigators.
4. Spouse Caregiver Criteria
    a. Spouse caregiver must be willing to participate in the trial.
    b. Spouse caregiver must be legally married, or file their tax returns as married filing jointly.*
    c. Spouse caregiver must be living in the same household with the eligible patient enrolling in this trial.
    d. Spouse caregivers must be at least 18 years of age.
    e. Spouse caregivers must provide their full name, primary address in the U.S., birth date and social security number at registration for the purposes of accessing credit report data.

f. Spouse caregivers must provide email and telephone number for the purposes of being contacted by the financial navigators.
g. Spouse caregivers must be able to complete questionnaires in English or Spanish and must complete the baseline questionnaires prior to patient registration.

*The study team acknowledges that other types of caregivers may also face financial hardship following a patient's cancer diagnosis and may similarly benefit from financial education and navigation. The decision to focus solely on *spouse* caregivers was scientific, to facilitate analysis of primary endpoint (household financial hardship).

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SCHEMA

Patient and spouse caregiver

Completion of baseline forms