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)

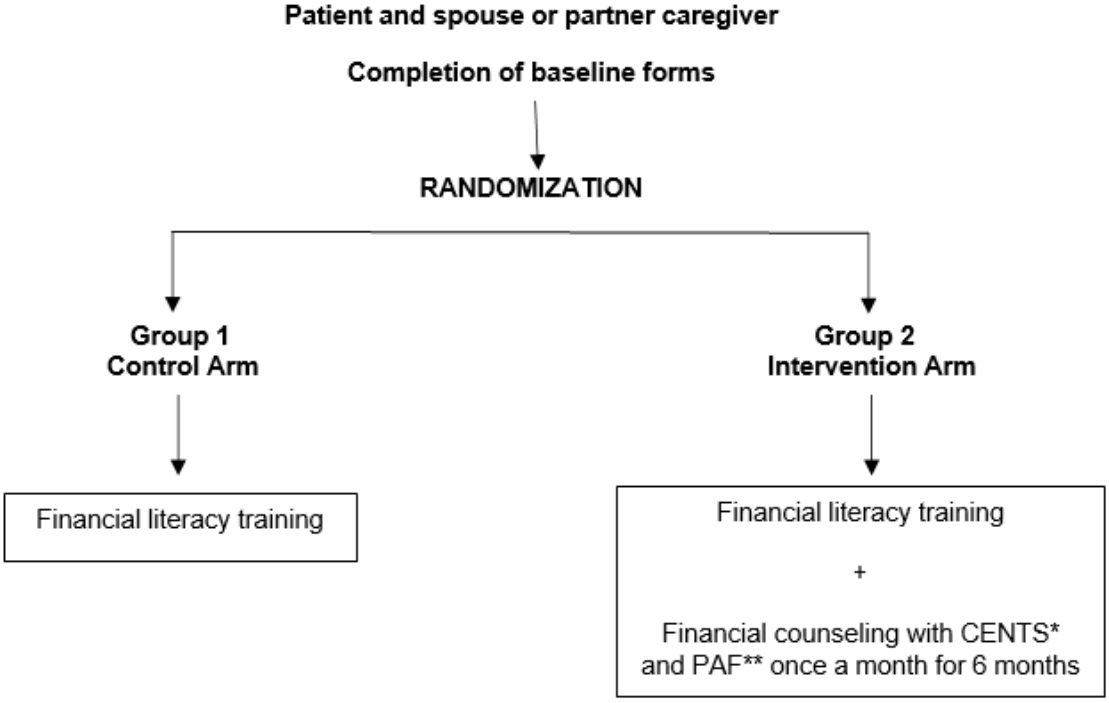
ELIGIBILITY CRITERIA

1. Disease Related Criteria – Patient
    a. Patients must have a diagnosis of a metastatic or stage IV 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 180 days after diagnosis of metastatic or stage IV solid tumor or treatment-requiring hematologic malignancy. Patients with indolent hematologic diseases undergoingobservation alone are not eligible; patients with previously diagnosed hematologiccancers progressed to the point of requiring systemic therapy are eligible, so longas the progression occurred within the previous 180 days. Biopsy confirmation of metastatic disease is not required.
    b. Patients with recurrent solid tumors will be allowed as long as 1) this is the first presentation of metastatic or stage IV 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, 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 90 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/or telephone number for the purposes of being contacted by financial navigators.
4. Spouse/partner Caregiver Criteria
    a. Spouse/partner caregiver must be willing to participate in the trial.
    b. Spouse/partner caregiver must be living in the same household with the eligible patient enrolling in this trial.
    c. Spouse/partner caregivers must be at least 18 years of age.

d. Spouse/partner 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.
e. Spouse/partner caregivers must provide email and/or telephone number for the purposes of being contacted by the financial navigators.
f. Spouse/partner 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 or partner* caregivers was scientific, to facilitate analysis of primary endpoint (household financial hardship).

SCHEMA



In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in Section 13.4.
* Consumer Education and Training Services (CENTS)
** Patient Advocate Foundation (PAF)