Cancer Research Consortium of West Michigan
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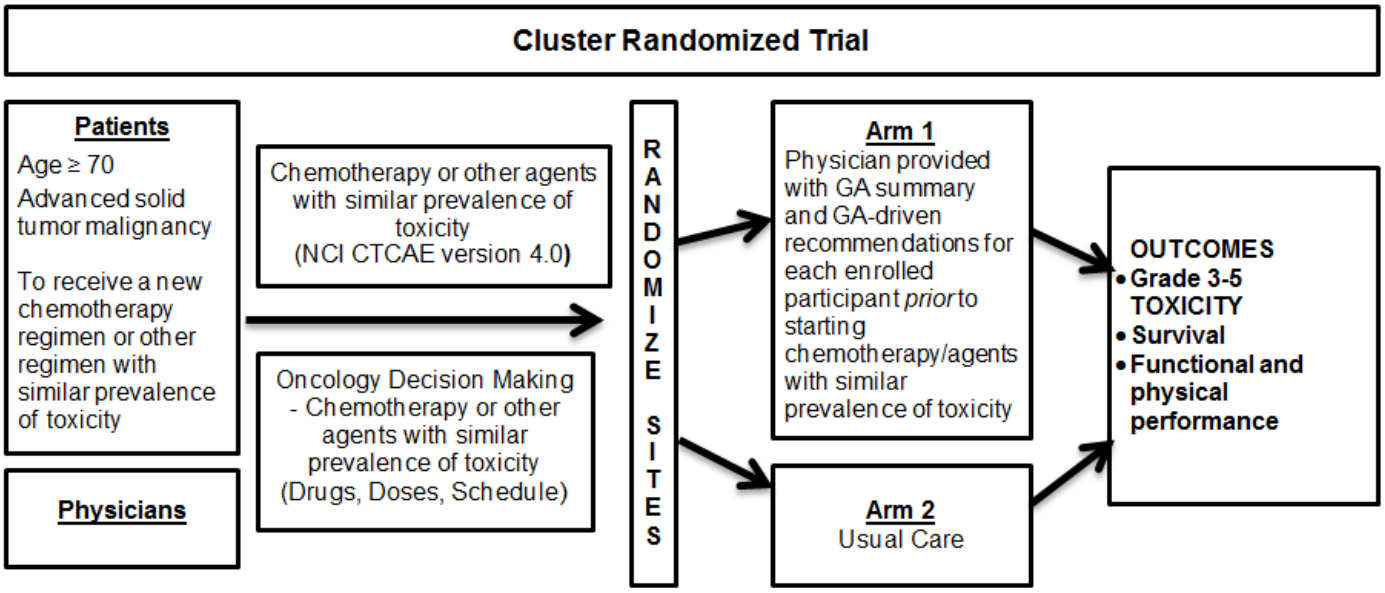
FAST FACTS

URCC 13059: A Geriatric Assessment Intervention for Patients Aged 70 and Over Receiving Chemotherapy or Similar Agents for Advanced Cancer: Reducing Toxicity in Older Adults

STUDY SCHEMA AND SUMMARY



INCLUSION CRITERIA

a. Male or female 70 years of age or older.

b. Diagnosis of an advanced solid tumor malignancy (advanced cancer) or lymphoma. In most situations, this would be a stage IV cancer. Patients with a diagnosis of stage III cancer or lymphoma are eligible if cure is not possible or anticipated. Clinical staging without pathological confirmation of advanced disease is allowed.

c. Plan to start a new cancer treatment regimen within 4 weeks from time of baseline registration. The treatment regimen is up to the discretion of the treating oncology physician. The regimen must include a chemotherapy drug or other agents that have similar prevalence of toxicity.

Patients who will receive monoclonal antibody therapy or other cancer therapies (e.g., tyrosine kinase inhibitors) are eligible if the other agents present a prevalence of toxicity similar to chemotherapy. These therapies can be used in combination with chemotherapy, as a single agent, or in combination with each other.

* Chemotherapy will be defined as cytotoxic drugs; in addition, agents (e.g., monoclonal antibodies and targeted agents) that have a prevalence of grade 3-5 toxicity in older patients similar to chemotherapy (>50%) will be allowed. A list of allowable agents (single and in combination) meeting this toxicity criteria will be available on the URCC NCORP Research Base website as part of the study materials. Given the rapidly changing landscape of new drugs for cancer, the study team led by the PI will update the list accordingly after reviewing the toxicity profile of new therapies. If the potentially eligible

participant is to receive an approved drug or regimen not on the list, contacting the URCC NCORP Research Base study team is required for approval prior to participant enrollment.
Patients who are receiving approved cancer treatment in combination with radiation are eligible.
A patient may also be enrolled on a treatment trial and participate in this study, if all other inclusion and exclusion criteria are met.

d. Plan to be on chemotherapy or other allowable treatment (as per 4.2.1c) for at least 3 months (minimum 70 days) and be willing to come in for study visits.
The plan for treatment should be for at least 3 months at time of study enrollment. The treatment can stop earlier during the study at the discretion of the physician and patient (e.g., due to progression as noted through imaging, toxicity, or patient preference).
e. Have at least one geriatric assessment domain meet the cut-off score for impairment other than polypharmacy per Table 1.
f. Able to provide informed consent, or if the oncology physician determines the patient to not have decision-making capacity, a patient-designated health care proxy (or authorized representative per institutional policies) must sign consent by the baseline visit. If the participant is found to be impaired on the Blessed-Orientation Memory Concentration Test (BOMC) during screening; they must have a health care proxy or authorized representative to be eligible to enroll.
g. Participant has adequate understanding of the English language because not all GA measures have been validated in other languages.

Exclusion Criteria for Patients

a. Have surgery *planned* within 3 months of consent. Patients who have previously received surgery are eligible.
b. Presence of symptomatic brain metastases at time of study consent process. Patients with history of treated brain metastases are eligible if they are not symptomatic at the time of study enrollment.

TREATMENT

Experimental: Arm I (GA intervention)

- Patients complete a geriatric assessment.
- Patients and physicians are provided with the geriatric assessment information and recommendations.

No Intervention: Arm II (usual care)

- Patients complete a geriatric assessment, but information other than clinically significant cognitive impairment and depression is not provided to the oncology teams.