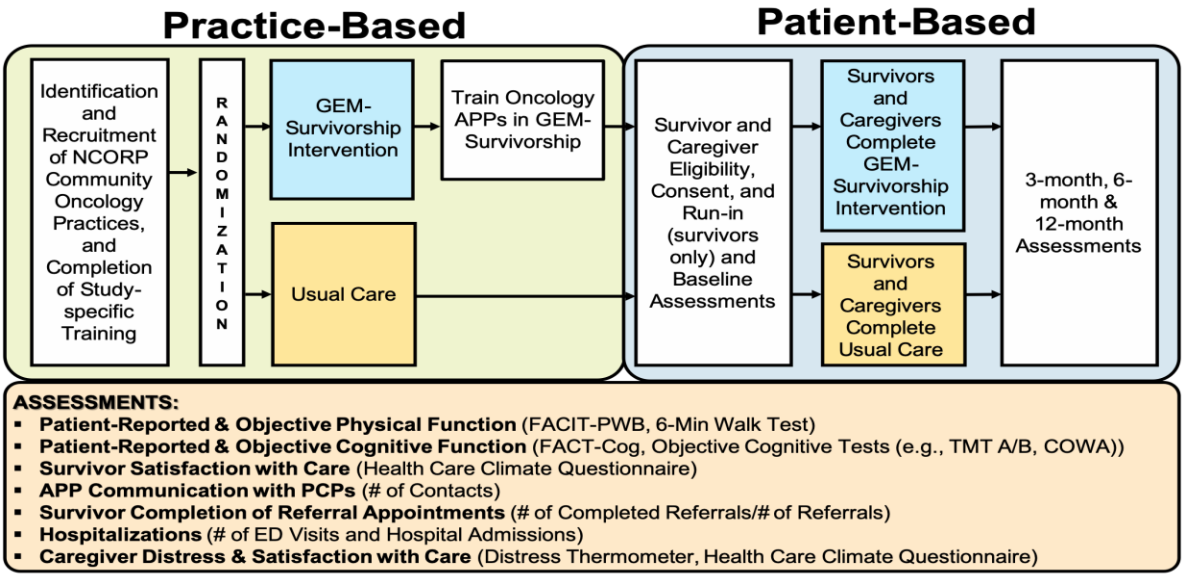

This study will evaluate whether a standardized intervention-Geriatric Evaluation and Management (GEM)[i] directed by an Advanced Practice Practitioner (APP) combined with Survivorship Health Education (GEM-Survivorship intervention)-can optimize outcomes important to the older cancer survivor after chemotherapy and their caregiver (if available).[ii] Adults aged 65 and older who have completed curative-intent chemotherapy for a solid tumor malignancy at a practice affiliated with the University of Rochester Cancer Center NCI Community Oncology Program (URCC NCORP) Research Base network will be eligible. Oncology physicians and APPs at practices within the URCC NCORP network are eligible to participate in the study. Eligible cancer survivors from their practices will undergo the informed consent process; those cancer survivors who agree to participate in this study will undergo an assessment including Sociodemographic Characteristics, Geriatric Assessment (GA), as well as the physical (e.g., FACIT-PWB)[1-3] and cognitive (e.g., FACT-Cog)[4,5] function assessments. Eligible cancer survivors should choose one caregiver to participate. Cancer survivors without an eligible caregiver can still participate (with permission from URCC NCORP Research Base). Participants (cancer survivors and caregivers) will be offered tele-health options to participate in certain study procedures if it is not convenient or feasible to complete these procedures in-person. Spanish-speaking cancer survivors and caregivers are eligible and can participate in the study as long as the local practice has the resources to complete procedures with the participants. See Sections 4 for Eligibility and 5 for Identification, Recruitment, and Informed Consent Procedures.

3. ELIGIBILITY

3.1. URCC NCORP Practice and APP Eligibility

URCC NCORP practices will be randomized within a 2-arm cluster randomized design utilizing "practice cluster" as the unit of randomization. Using methods developed in COACH,[24] a "practice cluster" will be defined as any practice location where staff (oncology physicians, APPs, coordinators) work independently (i.e., do not cross over). For example, for practice location A and practice location B, the three oncology physicians, and two APPs who work at both locations will form a practice cluster because they do not work independently at each practice. Each practice cluster will be expected to recruit a minimum of 10 and maximum of 40 cancer survivors to participate in the study. Based on our previous studies,[24] we anticipate enrolling approximately 30 practice clusters who will enroll 26 cancer survivors on average. During practice recruitment, if more practices meet eligibility criteria and are interested in participating, we will allow them to participate until cancer survivor enrollment is met. The total cancer survivor sample size will remain the same, and accrual will cease when that target is met.

Note: Once a practice cluster has been registered, the term "practice" encompasses the practice cluster. We will use "practice cluster" as a periodic reminder in certain parts of the protocol.

Practices which currently offer fully functioning survivorship care visits to patients will still be included.

NCORP practice and APP criteria:

3.1.1. Participating practice clusters will be required to identify one (or more) advanced practice practitioner (APPs; i.e., nurse practitioners or physician assistants) as part of study eligibility. APPs should provide a commitment for participating in training and study procedures.

1. *An APP should have experience in oncology or geriatrics to participate in the study.*
2. *All APPs must be licensed to practice.*
3. *APPs must not have a plan to leave or retire from the NCORP practice within two years of enrolling into the study.*

3.1.2. Desire to participate in the study, including presence of an investigator (e.g., NCORP PI, oncology physician, APP) and/or program administrator/supervisor who are willing to be key contacts.

3.1.3. Agreement that enrolled cancer survivors and caregivers (if available) will not formally be offered other survivorship plans or programs and that a Survivorship Health Education instructor(s) will be identified for the practice cluster.

3.1.4. Demonstrated support/buy-in from oncology physicians and/or APPs who are willing to enroll cancer survivors.

3.1.5. Agreement of practice leadership and staff (e.g., study coordinator) to support study activities.

3.1.6. Willingness to participate in an optional phone interview to determine capacity to implement the intervention.

We will enroll practices on a "first come, first serve" basis and continue to recruit until the cancer survivor enrollment is met. Recruitment procedures are described in Section 5.1. Overall, we aim to recruit so that 20% of practices enrolled are defined as rural or rural-serving using the Health Resources & Services Administration (HRSA) Rural Areas code classification developed by the Federal Office of Rural Health Policy (FORHP).[190,191] See Section 5.1 for more details.

3.2. Entry Criteria for Oncology Physicians

Oncology physicians must work at a URCC NCORP practice with no plans to leave that practice or retire within two years of enrollment into the study. We do not require that any or all oncology physicians at a practice setting agree to participate.

3.3. Entry Criteria for Cancer Survivors

3.3.1. Inclusion Criteria for Cancer Survivors

4.3.1a. 65 years of age or older.

4.3.1b. Have completed or will have completed curative-intent adjuvant chemotherapy for any solid tumor malignancy in last 4 weeks. Run-in study procedures can occur during the last 4 weeks of adjuvant chemotherapy but must be completed no later than 4 weeks after the completion of adjuvant chemotherapy.

Cancer survivors who will receive other curative-intent treatments (e.g., hormonal treatment, monoclonal antibodies, radiation) other than surgery are eligible.

4.3.1c. Be willing and able to come in for study visits or willing to undergo informed consent and assessments remotely via tele-health visits when necessary.

4.3.1d. Be willing and able to provide informed consent and must sign consent in-person or remotely if it is not convenient or feasible to provide informed consent in-person (Section 5.3.2).

4.3.1.1e. Speak and read English and/or Spanish. Spanish-speaking cancer survivors are eligible as long as there are appropriate resources in place for completion of study procedures at the practice site (Section 5.5). Registration for Spanish-speaking cancer survivors must be approved by the URCC NCORP Research Base after a phone call to determine the feasibility for the practice to enroll a Spanish-speaking participant.

3.3.2. Exclusion Criteria for Cancer Survivors

4.3.2a. Have surgery *planned* within six months of informed consent. Cancer survivors who previously had surgery are eligible.

4.3.2b. Have a condition that precludes their ability to participate in informed consent or procedures (e.g., dementia and/or Blessed Orientation Memory Concentration (BOMC) Score $\geq$11).[6]

3.4. Entry Criteria for Caregivers

For the purposes of this study, a caregiver is defined as a valued and trusted person in a cancer survivor's life who is supportive in health care matters by providing valuable social support and/or direct assistive care. The caregiver is able to listen and give thoughtful advice and may be a family member, partner, friend, or professional caregiver. **Cancer survivors choose one caregiver to participate.** Cancer survivors who cannot identify such a person ("caregiver") *can* be eligible for the study. Registration for cancer survivors who do not have an eligible caregiver must be approved by the URCC NCORP Research Base. *URCC Research Base staff should be notified by phone or the study email prior to patient registration if there is no designated caregiver.*

3.4.1. Inclusion Criteria for Caregivers

4.4.1a. 18 years of age or older.

4.4.1b. Selected by the cancer survivor when asked if there is a "*family member, partner, friend or caregiver [age 18 years or older] with whom you discuss or who can be helpful in health-related matters."* A caregiver need not be someone who lives with the cancer survivor or provides direct hands-on care.

4.4.1c. Speak and read English and/or Spanish. Spanish-speaking caregivers are eligible as long as there are appropriate resources in place for completion of study procedures (Section 5.5). Registration for Spanish-speaking caregivers must be approved by the URCC NCORP Research Base after a phone call to determine feasibility for the practice to enroll a Spanish-speaking participant.

3.4.2. Exclusion Criteria for Caregivers

4.4.2 Caregivers unable to understand the informed consent form or study procedures due to cognitive, health, or sensory impairment will be excluded.

Capacity to conduct informed consent procedures and study procedures will be determined by the coordinators in collaboration with the cancer survivors' oncologists. These procedures are similar to that of URCC 13070, which enrolled caregivers of older patients with advanced cancer.

4.42b. Have surgery *planned* within six months of informed consent. Caregivers who previously had surgery are eligible.

3.5. Survivorship Health Education (SHE) Instructors for GEM-S Intervention Arm

Practice cluster staff will be required to identify a qualified Survivorship Health Education (SHE) instructor if randomized to the GEM-S intervention arm. The SHE instructor must have a minimum of a Bachelor's degree in a health-related field (e.g., exercise science/kinesiology, health education, public health, nursing, psychology, social work, other). The SHE instructor is also required to have a professional fitness certification to perform exercise prescription and instruction (individual and/or group) via the American College of Sports Medicine (ACSM) or similar fitness certification organizations (e.g., American Council on Exercise, National Council on Strength and Fitness, National Strength and Conditioning Association, YMCA). ACSM Cancer Exercise Trainer certification is preferred, but not required. SHE instructors must also have ≥ 2 years of experience working with individuals who are cancer patients or survivors, or individuals with other chronic diseases or disabilities. It is strongly preferred that SHE instructors have experience working with older individuals. SHE instructor experience is required in the areas of teaching healthy lifestyle behaviors, prescribing individualized exercise and/or teaching group exercise classes.

The study MPI, Dr. Karen Mustian, and her research team, will be available to assist URCC NCORP practice clusters in selecting appropriate SHE instructors and all instructors have to be approved by Dr. Mustian or her designee. Each SHE instructor will be required to provide the following:

- Copy of his/her resume or curriculum vitae.
- Copy of the exercise professional certification.
- Documentation of his/her experience working with older patients with cancer or chronic diseases/disabilities.
- Personal liability insurance information.
- In order to be paid as a study consultant, the SHE instructor will complete:
    - An Internal Revenue Service (IRS) W-9 form.
    - A Professional Services Agreement.
    - An Independent Contractor Determination and Certification Form.
    - An Adherence Statement to ensure that the study intervention is delivered according to the protocol, SHE manuals, and PowerPoint presentations for SHE sessions.

The URCC NCORP practice cluster will submit these materials to the URCC NCORP Research Base (URCC_19178@urmc.rochester.edu) for review by Dr. Mustian or her designee to approve hiring the SHE instructor to teach the intervention.

Each SHE instructor will also be required to complete a one-on-one, 1 hour and 45-minute interview and training session with Dr. Mustian or her designee, before receiving final approval as a SHE instructor. SHE instructors will be asked to complete consent procedures for staff (Section 5.2.3) and participate in focus groups (Section 5.2).

A decision regarding the approval of the SHE instructor will be made within two weeks of providing all the necessary materials and completing the one-on-one interview and training with URCC NCORP Research Base. URCC NCORP practice cluster cannot hire and use SHE instructors that are not trained and approved by Dr. Mustian or her designee.

All SHE instructors will be paid directly as consultants by the URCC NCORP Research Base. Each SHE instructor must submit an invoice to the URCC NCORP Research Base (URCC_19178@urmc.rochester.edu) within 7 calendar days of completing the series of eight sessions for processing. Each SHE instructor will be paid a flat fee of $1200.00 to teach all eight sessions, which includes all training, preparation, class teaching, post class follow-up, and travel time; compensation is the same for in-person and tele-health SHE courses.