NCI Community Oncology Research Program

EAQ202

ECOG-ACRIN cancer research group

For Adolescents/Young Adults with Primary Cancer

EAQ202 Available Through ECOG-ACRIN Cancer Research Group

Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials

Patient Population

See Section 3.0 for Complete Eligibility Details

Selection of Sites: all interested NCTN, LAPS, and NCORP sites will be invited to participate (with a focus on MU NCORP sites)

Selection of Participants:

- Must be ≥ 18 years and ≤ 39 years of age
- Must have histologically confirmed diagnosis of primary cancer of any stage within 84 days of registration
- Must not have a recurrence or second primary cancer
- Must not have basal cell skin carcinoma
- Must have received, be currently receiving, or planning to receive treatment for cancer, including surgery and/or chemotherapy and/or radiation therapy
- Must have an ECOG PS 0-3
- Must have a life expectancy > 24 months
- Must be able to complete questionnaires in English
- Must have internet access through computer, tablet, or smartphone
- Must have an email address; must have a mobile phone with text messaging capabilities
- Must be able to accurately provide self-report data (e.g. per clinical judgement, cognitive function is intact)
- Must be able to provide informed consent
- Participants may be dually enrolled in EAQ202 and therapeutic trials, including those involving checkpoint inhibitors

Note: The breast cancer cohort closed to accrual 09/07/22.

Methodology Plan

See Section 5.0 for Methodology Details; Sections 6.0 & 8.0 for Site Completed Form Details; Section 7.0 for Questionnaire Details

- This is a two arm, randomized clinical trial that will explore the feasibility of measuring HRQOL among AYAs treated for cancer in academic and community settings
- Each participating site will complete one site survey, and one clinical form (per participant, per time point)
- The designated site CRN/CRA will work with physicians during the clinical session to identify/recruit patients
- Participants will be randomized (stratified by sex, age, race and ethnicity) and will rank the 15 domains from most to least important
  - ◊ Those assigned to the Choice PRO intervention arm will identify 5 (of the 15) HRQOL domains to complete at each time point
  - ◊ AYAs assigned to the Fixed PRO control arm will have domain-specific HRQOL measures fixed at each assessment (physical function, pain, cognitive function, social support, finances)
- Questionnaires will range from 82-112 items and can be completed in 13-18 minutes
  - ◊ These will be completed online through EASEE-PRO
    - ⇒ Participant characteristics, feasibility and acceptability items, health literacy, Global HRQOL (PROMIS), domain-specific HRQOL, service utilization and financial impact, AYA PRO feedback
- Patients will receive surveys at 5 time points over 12 months: baseline, 1 month, 3 months, 6 months, 12 months (all +/- 2 weeks); there is no further follow-up

Study Chair:
John M. Salsman, PhD

Co-Chairs:
Lynne I. Wagner, PhD
Ruth C. Carlos, MD
Ilana Gareen, PhD
Shira N. Dinner, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

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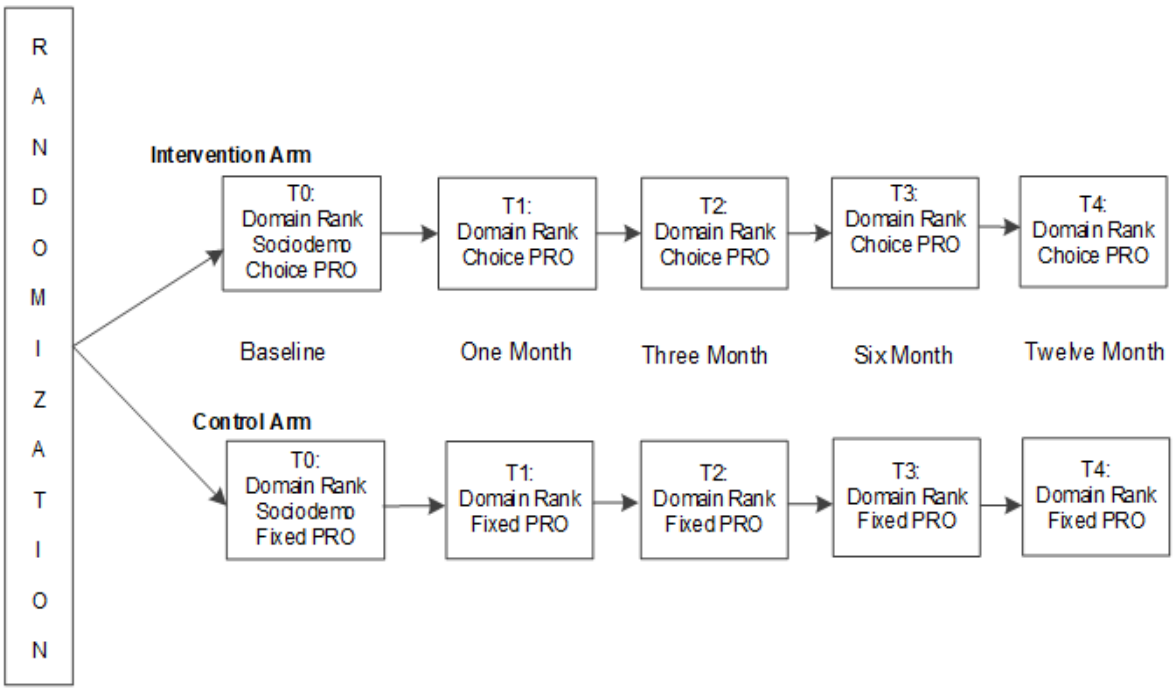
Schema



Eligibility:	**Randomization:**	**Domain Rank:**
-Age 18 to 39 -Within 12 weeks of diagnosis -Performance Status 0-3 -Any stage of cancer -Favorable prognosis	Stratified by sex, race, ethnicity, and age (emerging adults 18-25-year-old vs young adults 26-39-year-old)	Participant Ranks Domain by personal priority at each time point **Fixed PRO:** PROMIS Global, PROMIS standard AYA 5 domains, Common Items **Choice PRO:** PROMIS Global, 5 ranked AYA domains, Common Items

Accrual Goal = 400