

FAST FACTS

S2417CD - A Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of an Intervention: called Current Together After Cancer (CTAC) to Promote Guideline-Concordant Colorectal Cancer Surveillance

ELIGIBILITY CRITERIA

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient participant scheduling without exceeding the guidelines. If Day 28 falls on a weekend or holiday, the limit may be extended to the next working day.

Patient Participant Criteria

Disease Related Criteria

1. Patient participants must have newly diagnosed surgically resected, Stage II or Stage III colorectal cancer per the timing described in Section 5.1b.

2. Patient participants must have an adult in their life who supports them in their colorectal cancer journey who they might be willing to invite to join them in viewing an educational website. This is determined via the question:

“Do you have an adult in your life, such as a spouse/partner, family member or friend, who supports you with your colorectal cancer journey and may be willing to view a website with you? When we say, “supports you in your colorectal cancer journey”, we mean things like, helping you keep and get to medical appointments, talking with you and/or your doctors about your cancer, or helping you make decisions about your cancer.”

Those who respond “no” to the question above will be told that “Because this study is for patients and a supporter to view the website together, you are not eligible for this study, but there may be other studies you are eligible for in the future.”

NOTE: Online resources regarding Cancer Survivorship (i.e., American Cancer Society, the National Institutes of Health -Cancer Survivorship Website and Resources) can be shared with ineligible patients.

NOTE: The above question will be used to define “supporter” for purposes of this study. Examples of supporters include a spouse, partner, sibling, adult child, another family member, or friend.

NOTE: The supporter does not have to agree to participate in the study in order for the patient to be eligible for this study. Justification for requiring the enrolled patient to have a supporter (whether the supporter is invited or participates) is based on the study’s underlying conceptual framework (Section 2.2 and Figure 1).

3. Patient participants must not have recurrent or metastatic (Stage IV) colorectal cancer.

4. Patient participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the efficacy assessment of this intervention.

Prior/Concurrent Therapy Criteria

1. Patient participants must be registered within 90 - 180 days of surgical resection.

Clinical/Laboratory Criteria

1. Patient participants must be ≥ 18 years of age at the time of registration/randomization. The lower cutoff of 18 was determined because the lower age range of patients that may be recruited to SWOG studies is 18.

2. Patient participants must have Zubrod Performance Status of 0-2 (see Section 10.4).

3. Patient participants must be able to read English or Spanish since the website for the intervention and control arm are available in English and Spanish.

4. Patient participants must: 1) be able to complete Patient Reported Outcome (PRO) questionnaires in English or Spanish, and 2) agree to complete PROs at all scheduled timepoints (per Section 15.2).

5. Patient participants will be encouraged to provide an email address or cell phone number, if possible, for the purpose of being contacted by staff at the University of Michigan who will provide access to the educational website. For those who do not wish to provide or create an email address or a cell phone number, they may still participate with alternate methods.

NOTE: Option for patients who do not have an email address or cell phone number or choose not to use their personal email address or cell phone number are provided in Section 7.1d.1.

6. Patient participants must not be enrolled or be planning to enroll in a clinical trial of investigational treatment that includes imaging and/or laboratory monitoring for the duration of this trial.

NOTE: Patient participants are allowed to be co-enrolled on other non-treatment clinical trials.

Supporter Participant Eligibility Criteria

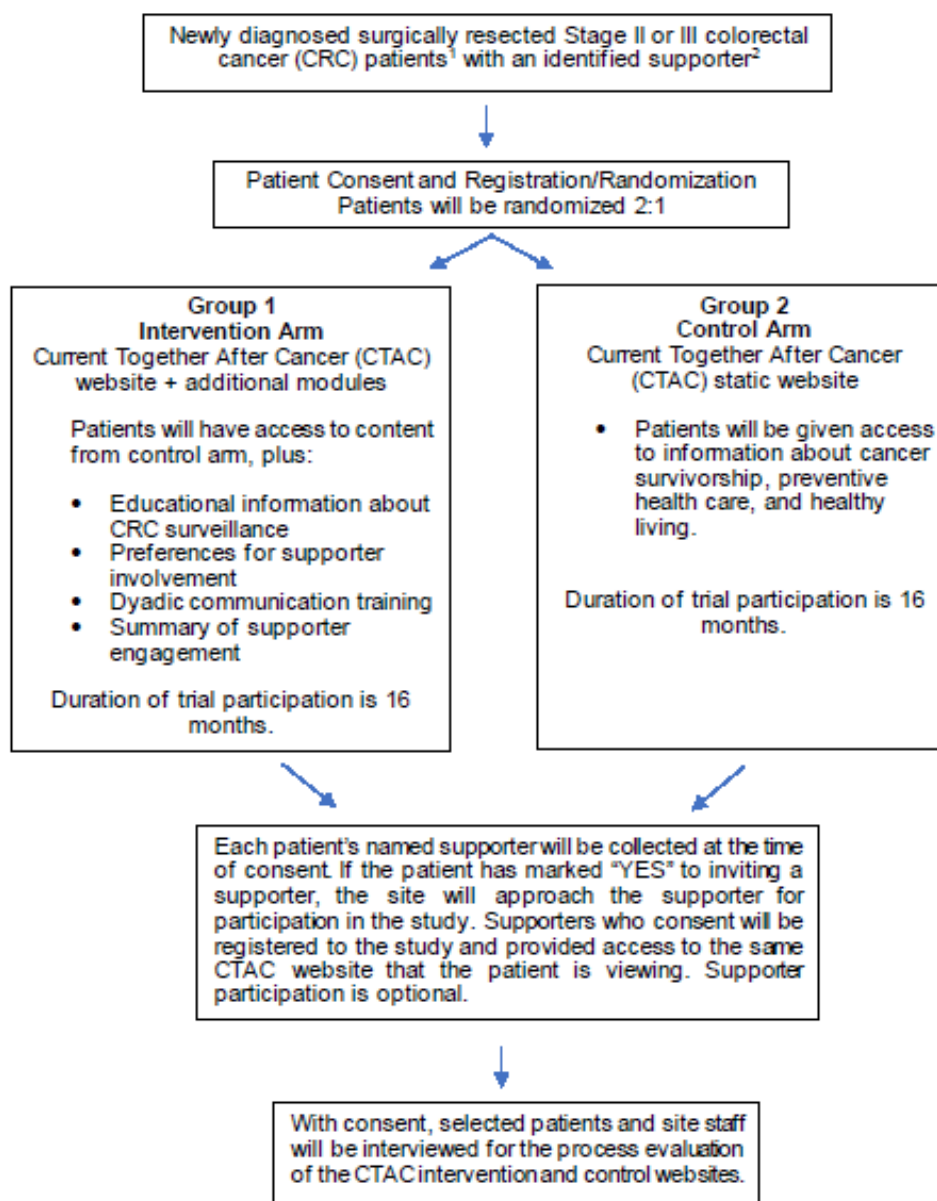
1. Supporter participants must be ≥ 18 years of age at the time of registration/randomization.

2. Supporter participants must be able to read English or Spanish since the educational website is available in English and Spanish.

3. Supporter participants must have been identified by the patient as a person who may be willing to join them in reviewing the educational website.

Regulatory Criteria (Patient and Supporter)

This protocol does not permit use of Legally Authorized Representative. Refer to Appendix 18.2 for remote consent allowance and link to CIRB SOP regarding remote consent procedures.



1 Patient = CRC Survivor

2 Supporter = Spouse/partner, adult child, other adult family member, friend