Clinical trial summary (S2417CD)

Can an Educational Website Help Improve Follow-up Care for Colorectal Cancer Survivors?

What is the purpose of this clinical trial?

After treatment for colorectal cancer, your doctor will likely ask you to continue with regular follow-up visits. Follow-up care often includes tests to check your health and watch for any new signs of cancer.

This clinical trial is about helping patients understand their health risks and the care they receive after cancer treatment. The trial will test an educational website for patients and their supporters.

- The website is designed to teach people about follow-up care that is recommended after finishing treatment for colorectal cancer.
- The website provides tools to help patients talk with their supporters about what type of support they want to receive

This trial is set up to find out:

- If the website helps patients receive follow-up tests that are recommended to check for new signs of cancer.
- If the website helps patients know more about their cancer risks and the importance of follow-up tests.

Why is this trial important?

Many patients are not getting the follow-up care that's recommended after colorectal cancer treatment. This trial aims to change that by helping people learn about the importance of regular check-ups and tests. The trial is a chance to see if a website made specifically for patients and their supporters can encourage people to take a more active role in managing their follow-up care.

Who can be in this trial?

This trial is for adults, ages 18 or older, who had stage 2 or 3 colorectal cancer.

This trial is for people who:

- Had surgery to remove the cancer
- Can read in English or Spanish
- Have a support person (such as a family member or friend) who might be willing to join the study

To join the trial with you, your support person must be an adult, age 18 or older. They must also be able to read in English or Spanish.

If your support person chooses not to join the trial, that's OK. You can still participate by yourself.

What can I expect during the trial?

This trial is about cancer care after treatment. You will not receive any medical treatment in the study.

A computer will randomly assign you to 1 of 2 groups.

Group 1	Group 2
You will be asked to visit a website that has information about health risks, follow-up care, and extra features for patients and supporters.	You will be asked to visit a website that has information about health risks and follow-up care.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.

If you join the trial, you will be given the option to invite your support person to take part in the trial too.

If your support person joins the study, they will be in the same group with you. They will be asked to view the same website as you.

Patients and supporters who join the study will:

Receive an email with a link to the study website.
You can visit the website on any laptop, desktop computer, tablet, or smartphone.

Create a personal account to access the website.
You can visit the website as many times as you want.

Patients in the study will also:

Complete surveys that ask questions about you, your health, and follow-up care after cancer treatment.

Have the choice to volunteer for a 1-on-1 phone interview for the study.
The interview is optional.

How long will I be in the trial?

Your part in the study will last about 16 months (1 year and 4 months).

You may choose to stop participating in the study at any time for any reason.

Are there costs? Will I get paid?

There are no costs for joining the study.

For patients: You can receive up to **$85 total** in gift cards for participating in this study.

- You will receive a $25 gift card for creating an account and visiting the study website.
- You will receive a $30 gift card for completing study surveys at Month 3.
- You will receive a $30 gift card for completing study surveys at Month 16.

For supporters: You will receive a $25 gift card for creating an account and visiting the study website.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **S2417CD**
- For a list of trial locations, visit swog.org/NCI-S2417CD

Key information

Protocol number: S2417CD

NCT number: [NCT number]

Trial sponsor: SWOG Cancer Research Network

Publishing date:

Full trial title: 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

Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.

S2417CD
A Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of an Intervention to Promote Guideline-Concordant Colorectal Cancer Surveillance

Study Chairs:
Christine Veenstra, MD, MSHP
Sarah Hawley, PhD, MPH

Patient Advocate:
Barbara Segarra-Vazquez, DHSc

Statisticians:
Joe Unger, PhD, MS
Amy Darke, MS

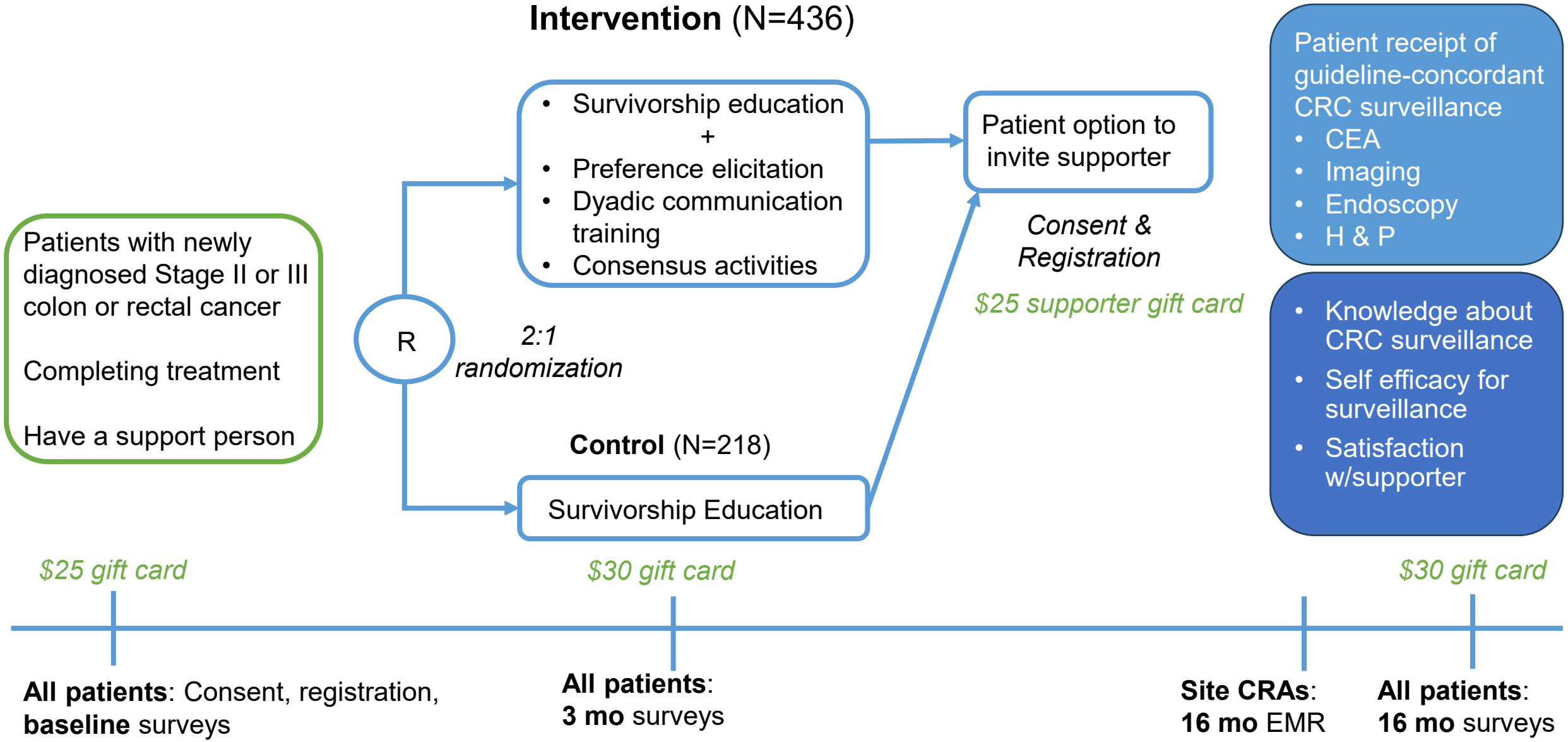
Data Coordinators:
Roxanne Topacio
Sam Dzingle

Protocol Project Manager:
Patricia O'Kane

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network

NCI Community Oncology Research Program



The CTAC website (both intervention and control) will be hosted by the University of Michigan.

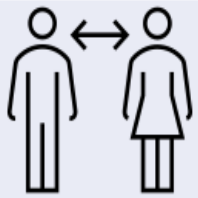
Background/Overview

- As many as 40% of patients with Stage II or Stage III colorectal cancer will experience cancer recurrence. Surveillance (CEA blood test, imaging, endoscopy, history & physical) may detect recurrences early.
- 60% of survivors don’t get guideline-concordant surveillance.
- There are gaps in knowledge about the purpose of surveillance and the risk of cancer recurrence.
- Patients who have a support person who is engaged in the surveillance process may be more likely to receive guideline-concordant surveillance.
- We developed Current Together After Cancer (CTAC) to educate patients about surveillance and help engage a support person in the surveillance process.

Current Together After Cancer

Online intervention for CRC survivors and their supporters

Figure 3. Components of Current Together after Cancer (CTAC)

Goal 1. Improve survivors' knowledge about surveillance and self-efficacy for navigating surveillance	**Goal 2.** Elicit survivors' preferences for supporter engagement in surveillance	**Goal 3.** Promote effective supporter engagement in surveillance
		
-Education about surveillance (purpose, components, risks of forgoing surveillance) -Information about and promoting ability to and confidence in obtaining surveillance care	Preference elicitation exercise for engagement of supporter for both survivor and supporter (or just survivor)	-Communication training for both survivor and supporter to promote aligned engagement (or just survivor) -Tailored communication checklist

Study Objectives

Primary Objective

- To evaluate whether patients in the Current Together After Cancer (CTAC) intervention arm (compared to the CTAC control arm) are more likely to receive guideline-concordant colorectal cancer (CRC) surveillance in the 12 months after randomization.

Secondary Objectives

- To assess in both arms at 3- and 16- months post-patient registration:
  - Patient-reported knowledge about surveillance
  - Patient-reported self-efficacy in management of surveillance, using previously developed CRC screening self-efficacy measure.
  - Patient-reported satisfaction with supporter engagement in surveillance.

Exploratory Objective

- To assess the implementation of CTAC into clinic workflow, and to better understand barriers and facilitators to the delivery of the intervention arm using a mixed-methods approached.

Stratification Factors

Patients will be randomized 2:1 to either Group 1 – CTAC Intervention Group or Group 2 – CTAC Control Arm with stratification by:

- Age <65 vs. Age 65 or older
- Male (yes vs. no)
- Spouse/partner support person vs. non-spouse/partner support person

Statistical Considerations

- Participants will be randomized at a 2:1 ratio to CTAC vs. control. This imbalanced randomization is predicated on the idea that a greater chance of receiving the intervention assignment will improve enrollment.
- **Target accrual is N=654 patients** (N= 436 in the intervention arm and N=218 in the control arm).
- Primary endpoint will be analyzed under the intention-to-treat principal among all eligible participants (regardless of whether their supporter is involved).

Key Eligibility – Patient Participants

- Must have newly diagnosed surgically resected, Stage II or Stage III colorectal cancer.
- Patient participants must be registered within 90-180 days of surgical resection.
- 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 the educational website.
  - NOTE: If the patient answers “no” indicate that they , they will not be eligible to participate. *If a patient does not wish to invite a supporter to participate in the research or if the supporter does not agree to participate, then the patient is still eligible.
- Must NOT have recurrent or metastatic (stage IV) colorectal cancer
- Must NOT have a prior or concurrent malignancy whose natural history or treatment has the potential to interfere with the efficacy assessment of the intervention
- ≥ 18 years of age, Zubrod PS 0-2, able to read English or Spanish, and willing to provide an email address or cell phone number for the purpose of being contacted by staff at the University of Michigan who will provide access to the educational website.
- 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.

Key Eligibility – Supporter Participants

- ≥ 18 years of age.
- Able to read English or Spanish.
- Identified by the patient as a person who may be willing to join them in reviewing the educational website.

Patient Recruitment

- Site staff should conduct regular and frequent chart reviews to identify potentially eligible patients.
- **Phone, email, or portal recruitment**:
  - Site staff can reach out to patients using provided telephone scripts and/or email/portal message templates to assess patient interest.
  - Phone messages, emails, and portal messages must include a local research department phone number and email address so that patients can call back or reply to email if interested.
  - The S2417CD patient information sheet will be available in English and Spanish and can distributed via email for remote discussions.
- **In-person recruitment:**
  - The S2417CD patient information sheet will be available in English and Spanish and can be used to help recruit patients during clinic visits.
- Template language will be provided in a protocol appendix.

Implementation Alternatives: E-mail address

- **E-mail address**:
  - If a potential patient does not have an email address or does not want to provide their personal email address, sites may suggest that patients create an email account with a free service in order to receive the study-specific website link and eGift cards from the University of Michigan team.
  - If not willing or able to set up a free E-mail address:
    - Patients who have a smartphone will receive a text message from University of Michigan staff with a link they can click on to access their assigned website.
  - If no E-mail address or smartphone:
    - University of Michigan staff will provide the URL to the patient's assigned website via an email to the participating site's designated study coordinator to convey to the patient.

Implementation Alternatives: Internet Access

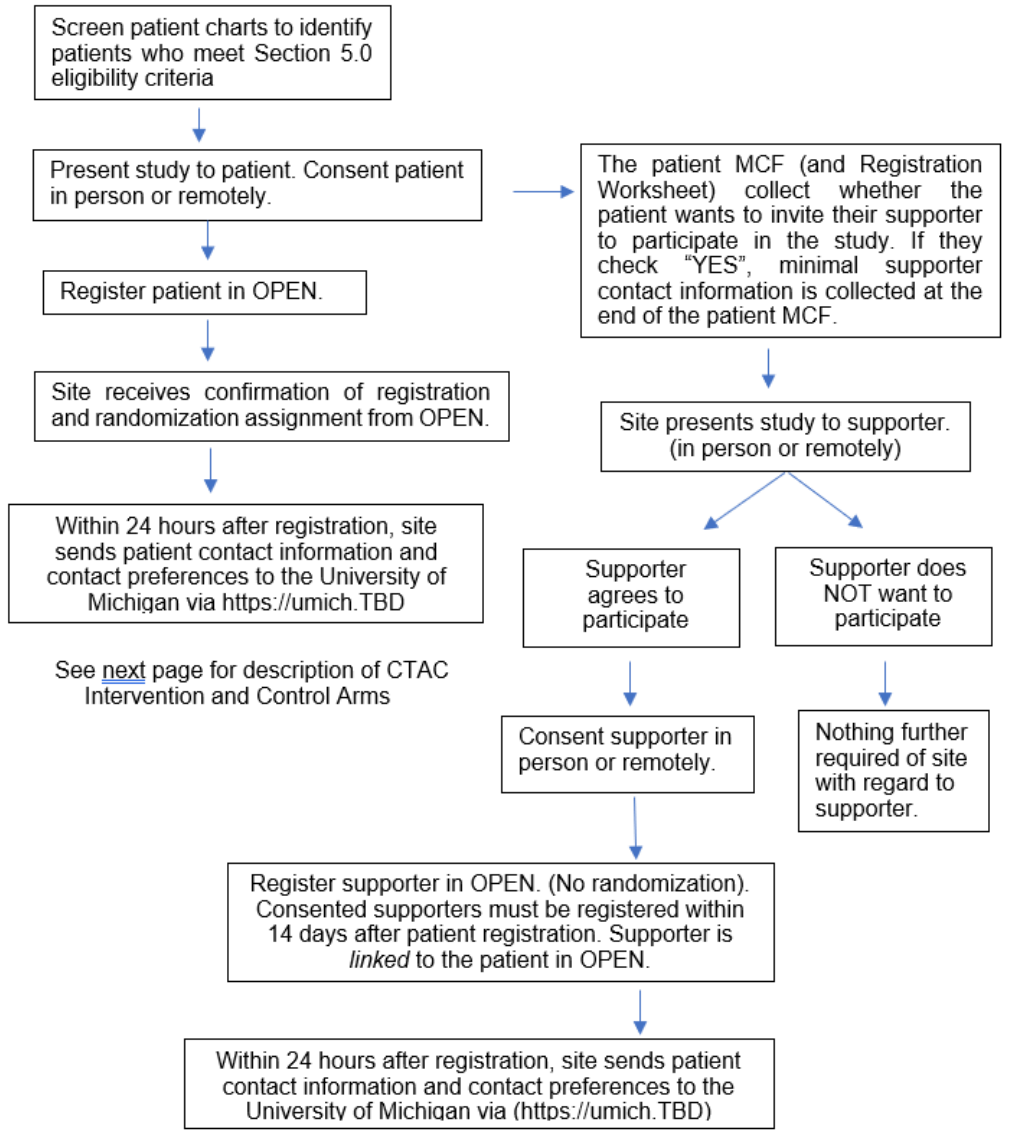
- **If the patient participant does not have home internet access or computer/device**:
  - The website may also be viewed on a device owned by a friend or family member, or in the public library.
  - A limited number of iPads/tablets will be made available **for in-clinic use** to support recruitment of patients who do not have home internet access.
  - Sites may request an iPad for the study period if they believe that most of their identified patients will not have home computer/internet access.

Group 1: Patient and Supporter Participants: Combined CTAC Intervention Website Viewing Preference

- While not a study requirement, for patients that invited a supporter: It is preferable for patients and participating supporters to view the CTAC intervention website together because Modules 3 and 4 include interactive dyadic components that, while they can be done separately and shared, may be more helpful for patients and supporters if they can view the content together in real time.
- This preference will be stated at time of patient and supporter log in and when patients are alerted that their supporter has agreed to participate.

Site Activities Workflow

- Important: It is critical for sites to register consented supporters in a timely manner (within the 14-day window) so that the patient and supporter can view the website together if possible.



Study Workflow for Randomized Patients

- Patient receives CTAC link and creates account / password.
  - Account creation prompts eGift Card emailed from U Mich.
- Patients who do not create an account within 1 week will receive email reminder. Then, weekly reminders will be sent up to 2 more times.
  - Patients who do not create an account **after 21 days** will still receive follow-up assessments.
- CTAC website notifies the patient that their supporter has been registered.
- Patients who do not invite a supporter can still participate in the study including viewing their respective website (CTAC intervention or control).
- Patient completes Baseline Forms within 14 days after registration. There is a window of ± 14 days for administration of PROs for the follow-up timepoints.

Notes:
- For Group 1: The intervention website includes communication skills training.
- In addition to account creation, eGift cards will also be provided to patients upon completion of PROs at 3 months, and 16 months.
- U Mich staff will contact and consent site staff and a subset of patients for CTAC process evaluation interviews.

Study Workflow for Supporters

- Supporters will receive a link to the same website that the patient is viewing.
  - Account creation by the supporter prompts eGift Card from U Mich.
  - CTAC website notifies the patient that their supporter has been registered.
- Supporters will be able to voluntarily participate in CTAC together with the patient on the same device or on a different device in a separate location.

Paradata Collection

- U Mich will collect CTAC paradata from all participants (patients and supporters on both arms) to help understand usage patterns, including:
  - Total time spent on the website
  - Pages viewed
  - Time on individual pages
  - “Drill downs” into sub-sections
  - Return to website
  - Whether pages were printed out
  - Whether supporters who did participate, did so together with the patient or remotely

Criteria for Removal of Patient from Protocol Participation

- Patient completes 16-month assessment
- Patient death
- Recurrence of disease
- The patient may withdraw from the study at any time for any reason
- Note:
  - Patients who are registered to the study will continue to receive follow-up assessments, even if they never create an account in CTAC.
  - If the patient allows for indirect follow-up or is refusing to complete any further participant forms but will allow the site to follow them, site staff will continue to submit the site completed forms at the time points indicated in the protocol.
  - Research staff should only submit the "S2417CD Off Protocol Notice – Patient" if the patient ***refuses both direct and indirect follow-up*** on the study.
  - Supporters may choose to stop participating at any time for any reason.

Discontinuation of Protocol Participation and Follow-up

- All reasons for discontinuation of protocol must be documented in the S2417CD Off Protocol Notice – Patient.
  - Note: If a patient cannot or refuses to complete the participant questionnaires for a study time point, this is not a criterion for discontinuation of protocol participation.
- **No further follow-up of the patient will be required of the sites after the patient completes the 16-month assessment or if the patient discontinues protocol participation.**
  - If the patient agreed to be contacted for interview participation, this may occur after the completion of the 16-month assessment.
  - There is no follow-up for supporters as they do not participate in protocol assessments.

Participant Registration

Patients

- Patients must be registered within 90-180 days after surgical resection.

Supporters

- Consented supporters must be registered within 14 days after patient registration.

For All Participants (Patients and Supporters)

- Within 24 hours after registration, the site must complete the **S2417CD** Participant Contact Preferences Form. This form will allow the participant ID, participant contact information, and preferences for receiving the website link and eGift cards to be sent securely and efficiently to the University of Michigan.

Data Submission

- The Medidata Rave® clinical data management system is to be used for all data submission. Access to the S2417CD in Rave will be controlled through the CTEP-IAM system and role assignments.
- Data must be submitted according to the protocol requirements for ALL participants registered, whether or not assigned treatment is administered, including participants deemed to be ineligible.
- Complete Data Submission Requirements, Procedures and Timepoints will be included in Protocol Section 14.
- A printable (.PDF) version of the Master Forms Set will be accessible from the S2417CD protocol abstract page on CTSU.org.
- Sites will be required to submit an online **S2417CD** Site Attributes survey within 14 days after the randomization of the first patient. This survey is completed only **once** at the beginning of the study / first patient enrollment.

Patient Reported Outcomes

PROs are assessed at three timepoints:

1. Baseline
2. 3-months post registration
3. 16-months post registration

Participants should continue to complete questionnaires at study timepoints regardless if participant discontinues the study intervention early.

Instrument	# of questions	Time for completion	Timepoints
S2417CD Patient Demographics and Health Literacy	8	Approximately 2 minutes	Baseline only
S2417CD Knowledge About Surveillance	5	Approximately 2 minutes	Baseline, 3 months, and 16 months after registration
S2417CD Cancer Worry Scale	8	Approximately 2 minutes	
S2417CD Follow-Up Care Preferences	9	Approximately 2 minutes	
S2417CD Self-Efficacy for Managing Follow-Up Care	6	Approximately 2 minutes	
S2417CD PROMIS® - 29 + 2 Profile v2.1 (PROPr)	4	Approximately 2 minutes	
S2417CD Satisfaction with Supporter Engagement	7	Approximately 2 minutes	3 and 16 months
S2417CD Receipt of CRC Surveillance – Patient Reported	9	Approximately 2 minutes	At 16 months

Patient Reported Outcomes

Distribution of PRO Questionnaires by Sites:

- Paper copies of questionnaires may be provided to consented patients in-person, by mail, or email.
  - If a patient chooses to submit PROs by regular mail, the site will use NCORP funding to cover the costs of self-addressed, stamped envelopes.
  - If the questionnaire is emailed, the patient must print, complete, and return the form to the site.

Administering PRO Questionnaires:

- Questionnaires will be self-administered.
- Target follow-up assessment dates should be based on the date of registration (±14 days)
- Questionnaires can be completed at home by the patient and returned to the site.
- At first completion timepoint: Please read the instructions attached to the participant questionnaire to the participant. Explain the specific administration times for this protocol.
- Site CRAs can assist participants with completing questionnaires being careful to not influence the patient's response. Patients must be able to communicate their choices to the person assisting them.

Cover Sheet for Patient PRO Questionnaires:

- For each time point, site staff must complete and submit the S2417CD Cover Sheet for Patient-Completed Questionnaires. If a patient-completed form is not administered at a scheduled time point, document reasons in the Cover Sheet.

Patient Reported Outcomes

Options for completing questionnaires

- **At home (most common)**: Provide the patient with the questionnaires in advance and instruct them to return the questionnaires to the site in person or by mail
  - Provide a pre-paid, pre-addressed envelope for patient to return the questionnaire by mail if needed
  - Review the returned questionnaire for completeness and follow up with patient by phone to review incomplete questions
  - Completed questionnaires can be scanned and returned via email if the site has a secure, encrypted email
  - NOTE: Questionnaires can be emailed to the patient. However, the patient will have to print, complete, scan, and return the questionnaires on their own

Patient Reported Outcomes

Options for completing questionnaires, cont'd

- **In clinic**: When possible, provide a private location for the patient to complete the questionnaire. Review the questionnaire immediately for completeness and review incomplete questions with the patient.
  - Incomplete questionnaire in clinic: Make a copy of the incomplete questionnaire, give the patient the copy and keep the original. Provide the patient with a pre-paid, pre-addressed envelope to return the questionnaire after they finish it at home.
  - After the questionnaire is returned, follow up with patient by phone to review incomplete questions.

- **Phone or videoconference interview**: Phone or video conference interviews should be scheduled within 1 week of the study time point.
  - Provide the patient with a copy of the questionnaire for them to review during the interview.

Process Evaluation Interviews: Subset of Patients and Site Staff

Using Consolidated Framework for Implementation Research (CFIR)

Objectives:

1. Assess the implementation of CTAC into clinical practice
2. Understand barriers/facilitators to delivery of CTAC
3. Understand barriers/facilitators to inclusion of supporters in CTAC

20-30 minute interviews with **20 patients from intervention arm, 20 patients from control arm,** and **10 study staff**

$30 gift card distributed via email (or alternate method) after completion of interview.

Quality Assurance and Study Monitoring

- Audits will be conducted at frequency of 3 years.
- The SWOG Data and Safety Monitoring Committee will oversee the conduct of the study. The Committee consists of four members from outside of the SWOG Cancer Research Network, three SWOG members, three non-voting representatives from the NCI, and the Group Statistician (non-voting).
- Members of the committee will receive and review confidential reports every 6 months from the SWOG Statistics and Data Management Center. Accrual and feasibility will be the focus of the review.
- The committee will meet bi-annually as necessary.

Informed Consent for Patients and Supporters

Both patients and supporters may be consented in-person or remotely and will be registered in OPEN after they consent to participate in the study.

Patients

- Patients interested in participating in the study may be consented in-person or remotely.
- At the time of consent, patients will be asked:
  - If they would like to invite a support person to participate in the stud and view the educational website.
    - If Yes: The patient will be asked to provide the supporter's name and contact information. Note: Supporters who subsequently consent to participation should be registered in OPEN within 14 days of patient registration in OPEN.
  - For permission for the study team to contact the patient at the end of the study to discuss the possibility of participating in an optional audio-recorded (30-minute) interview.
    - If Yes: The **University of Michigan** will subsequently contact the patient to obtain consent for participation in patient interviews. Note: Supporters will not be asked to participate in interviews.
  - If they may be contacted to see if they wish to participate in future research.

Patient Advocate Perspective

- Very enthusiastic about this study. Understanding early on the importance of surveillance and what is needed, will help patients advocate for themselves.
- When to approach the patient to invite them to participate is crucial. Avoid approaching when they are receiving a new results or discussing treatment options, they can be overwhelmed.
- Having the different options to complete questionnaires will allow to accommodate people from different ages and literacy. For me, the time estimation for questionnaires completion could be underestimated, so allow for more time if you are helping the participant or when you explain the time it will take them to complete it.

Presented on behalf of Barbara Segarra-Vazquez, DHSc, Cancer Care Delivery Committee Patient Advocate & SWOG Patient Advocate Committee Co-chair

Funding

S2417CD is limited to sites equipped to conduct Cancer Care Delivery Research (CCDR) and that have been approved by the Study Chair's office to participate in the trial. CCDR restricted funds have been distributed directly to sites and can be used to support CCDR studies.

S2417CD is planned to include participant gift cards funded by an NIH/NCI R01 grant. Funds will be distributed by the University of Michigan directly to participants.

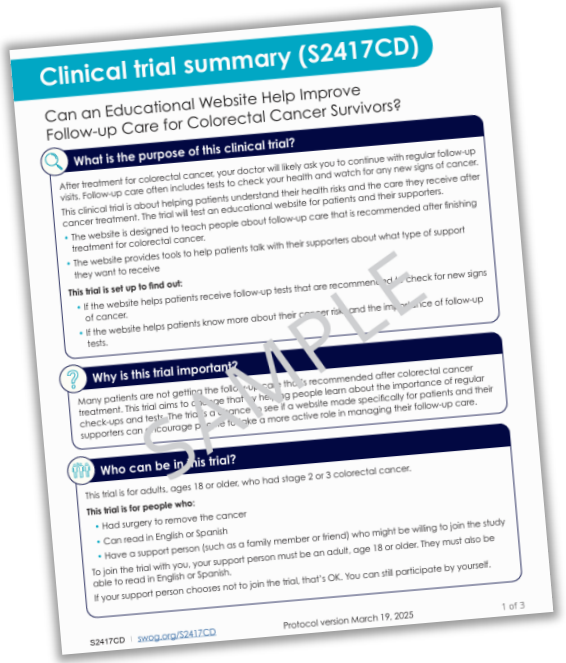
Intended funding amounts – pending approval

Recipient	Description	Time Points/Trigger	Amounts
Participant		Account creation within the control or CTAC intervention website	$25
Participant	Follow-up	M3, M6	$30/timepoint
Participant	1-on-1 process evaluation interview for select participants	Interview completion	$30
Patient Support		Account creation within the control or CTAC intervention website	$25
Enrolling Site Staff	One-time interview related to the process evaluation for select staff	Interview completion	$30

Resources and Materials — Patient-Friendly Clinical Trial Summary

The Patient-Friendly Summary is an educational tool to share key information about the trial

- Easy to understand, written in plain language
- Explains why the study is important, study treatments, who is eligible, length of trial involvement, costs, and how to learn more
- May include graphics to illustrate study design or treatments
- Translated into Spanish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What is the purpose of this clinical trial?

After treatment for colorectal cancer, your doctor will likely ask you to continue with regular follow-up visits. Follow-up care often includes tests to check your health and watch for any new signs of cancer. This clinical trial is about helping patients understand their health risks and the care they receive after cancer treatment. The trial will test an educational website for patients and their supporters.

- The website is designed to teach people about follow-up care that is recommended after finishing treatment for colorectal cancer.
- The website provides tools to help patients talk with their supporters about what type of support they want to receive

This trial is set up to find out:

- If the website helps patients receive follow-up tests that are recommended to check for new signs of cancer.
- If the website helps patients know more about their cancer risk and the importance of follow-up tests.

Why is this trial important?

Many patients are not getting the follow-up care that is recommended after colorectal cancer treatment. This trial aims to change that by helping people learn about the importance of regular check-ups and tests. The trial is a chance to see if a website made specifically for patients and their supporters can encourage people to take a more active role in managing their follow-up care.

Who can be in this trial?

This trial is for adults, ages 18 or older, who had stage 2 or 3 colorectal cancer.

This trial is for people who:

- Had surgery to remove the cancer
- Can read in English or Spanish
- Have a support person (such as a family member or friend) who might be willing to join the study

To join the trial with you, your support person must be an adult, age 18 or older. They must also be able to read in English or Spanish.

If your support person chooses not to join the trial, that's OK. You can still participate by yourself.

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SAMPLE

We recommend a study team member review the summary with the patient as an introduction to the trial, or alongside the consent

- Also available as a PDF to be printed or shared electronically

The summary will be accessible from:

- **swog.org/S2417CD** (publicly accessible link, with printable PDF)
- Also via the S2417CD protocol abstract page on CTSU.org under Documents >> CIRB Approved Documents tab >> Support Documents filter, listed as “Clinical Trial Summary” (login required)

Additional Resources and Materials

- S2417CD Social Media Toolkit (text and graphics) will be available via the S2417CD protocol abstract page on CTSU.org under
  - Documents>>CIRB Approved Documents tab>> Support Documents filter

Questions?

Contact:
Christine Veenstra, MD, MSHP: cveenstr@med.umich.edu
Sarah Hawley, PhD, MPH: sarahawl@med.umich.edu

SWOG Protocol Project Manager: Patricia O'Kane pokane@swog.org

Open Forum:
Q & A / Discussion

Thank you