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The COMPASS study: A prospective, randomized, multi-center trial testing the impact of a clinic-based intervention informing patients of colorectal cancer screening options on screening completion

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Abstract

Background: Colorectal cancer (CRC) screening is underutilized despite evidence that screening improves survival. Since healthcare provider recommendation is a strong predictor of CRC screening completion, providers are encouraged to engage eligible patients in collaborative decision-making that attends to patients' values, needs, and preferences for guideline-concordant screening modalities.

Methods: This three-arm randomized controlled trial is testing the effectiveness of an evidence-based video intervention informing patients of screening choices delivered in a clinic prior to a healthcare appointment. We hypothesize that participants randomized to watch a basic video describing CRC and screening in addition to an informed choice video showing the advantages and disadvantages of fecal immunochemical test (FIT), stool DNA FIT (s-DNA FIT), and colonoscopy (Arm 3) will exhibit a greater proportion of time adherent to CRC screening guidelines after 1, 3 and 6 years than those who only watch the basic video (Arm 2) or no video at all (Arm 1). Primary care and Obstetrician/Gynecology clinics across the United States are recruiting 5280 patients, half who have never been screened and half who previously screened but are currently not guideline adherent. Participants complete surveys prior to and following an index appointment to self-report personal, cognitive, and environmental factors potentially associated with screening. Proportion of time adherent to screening guidelines will be assessed using medical record data and supplemented with annual surveys self-reporting screening.

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Conclusion: Results will provide evidence on the effectiveness of informational and motivational videos to encourage CRC screening that can be easily integrated into clinical practice.

Keywords

Clinical trial; Early medical intervention; Colonic neoplasms; Colorectal cancer screening; Early detection of screening; Behavior change theory

1. Background

In the United States (US), colorectal cancer (CRC) is the second leading cause of cancer-related deaths for men and women combined [1–3]. CRC screening improves early detection and reduces risks of cancer-related mortality [4]. Several effective, guideline-endorsed early detection screening modalities are available, including stool-based and direct visualization tests [4]. Stool-based tests include fecal immunochemical test/guaiac-based fecal occult blood tests (FIT/gFOBT), recommended to be completed annually, and combined stool DNA plus FIT (s-DNA-FIT) tests, recommended to be completed every three years. A common direct visualization test, colonoscopy, is recommended every ten years. All CRC screening modalities have high certainty of net benefit, but each varies regarding safety, efficacy, cost, and patient acceptability [4].

Healthy People 2030 and the National Colorectal Cancer Roundtable have set screening goals to exceed screening in >75% of people ages 50–75 years in the US [5,6]. As of 2020, however, <66% of adults in that age group were guideline concordant [5]. CRC screening is underutilized in groups with higher rates of incidence and mortality, including racial and ethnic minorities, people with lower socioeconomic status (SES) [7] and those with disabilities [8]. Younger adults also have lower screening rates, with only 50% of those ages 50–54 having been screened [3]. With recommendations from the US Preventive Services Task Force (USPSTF) and American Cancer Society (ACS) recently updated to include average-risk adults ages 45–49 [1,4], greater effort may be needed to meet national screening targets.

The COVID-19 pandemic has created additional challenges for attaining national CRC screening goals. Compared to 2019, claims for screening colonoscopies in 2020 dropped 27%, likely due to restrictions on non-urgent and elective procedures at healthcare facilities and recommendations early in the pandemic to delay CRC screening [9]. These restrictions and resultant changes to clinical practice have shifted attention to the benefits of home-based healthcare including stool tests for CRC detection [10]. Improving screening rates will likely require targeted efforts for use of all screening modalities, and therefore, interventions to promote informed choices about CRC screening modalities are in demand.

Knowledge about CRC and CRC screening, and attitudes and beliefs about screening are associated with a patient's intention to screen [11,29,30]. Intentions to screen, however, do not reliably predict screening completion [12,13]. Intervention efforts must address individual-level factors, such as knowledge, attitudes, and beliefs, as well as social and healthcare systems factors that influence screening. Provider recommendation is a key

predictor of CRC screening completion [14–16] especially when recommendations align with patient preferences for a specific screening modality [17,18]. Despite healthcare providers recognizing that collaborative decision making that attends to patient preferences improves screening uptake [4,19–24], shared decision-making for CRC screening is underutilized [18,25]. Colonoscopy remains the preferred screening modality among healthcare providers [26] and is frequently offered to patients without providing them information about other screening modalities. As more CRC screening modalities become available, questions remain regarding how to effectively provide comprehensive education to prepare patients to engage in informed decision making about CRC screening, especially in clinical environments where time is scarce [27].

Our study's objective is to test the impact of an informed choice patient education video viewed prior to a preventive health visit on the proportion of time patients are adherent to CRC screening guidelines. Our hypothesis is that providing patients with an informed choice video that includes salient, standardized information about CRC screening modalities (colonoscopy, FIT, and s-DNA-FIT), descriptions of screening barriers, and prompts to encourage patient-clinician discussions about screening options that fit patient needs and preferences [26] will result in greater proportion of time adherent to CRC screening guidelines compared to those who view a video with basic CRC information or no video. Our secondary objective is to examine screening modality preferences across the three study conditions. We also have two exploratory objectives; 1) evaluate if participant, environmental, and cognitive factors predict intentions to screen, and in turn, CRC guideline adherence; and 2) determine if healthcare provider, system, and site-level factors are associated with CRC guideline adherence and use of specific screening modalities.

2. Methods

2.1. Study design

This multi-site, prospective, randomized, controlled study of adults at average risk for CRC with upcoming primary care appointments compares the percentage of time that participants are adherent to CRC screening guidelines (i.e., percentage of time covered, or PTC) at 1, 3, and 6 years after being randomized to receive either usual care without a video intervention (Arm 1), a basic video developed in collaboration with the American Cancer Society (ACS) (*ACS basic video)* describing CRC and the importance of CRC screening (Arm 2), or the same ACS basic video with additional information on 3 modalities available for CRC screening (*ACS basic + informed choice)*(Arm 3). Colonoscopy, FIT, and s-DNA FIT were chosen because they are the most frequently used CRC screening modalities in the US [1]. We are not including CT colonography because this is not a covered insurance benefit for most individuals, nor are we including flexible sigmoidoscopy since it is not widely available/used. All a-priori hypotheses are in Table 1.

2.2. Theoretical approach

The study design, videos, intervention development, and data collection tools are informed by behavioral theory and prior research. Expounding on a model from the SCREEN study [28,29] that integrates Social Cognitive Theory (SCT) [30] and the Theory of Planned

Behavior (TPB) [31], we propose that screening completion and adherence are influenced by individual-, social- and environmental-level factors (Fig. 1). Individual factors include *personal and cognitive factors. Personal factors* include sociodemographic factors, physical and cognitive function, quality of life, and level of health literacy. *Cognitive factors* include knowledge about CRC and screening, self-efficacy, and attitudes and beliefs about medical care, such as trust and acceptance of medical advice. Attitudes and beliefs about screening are characterized as desirability of engaging in screening and beliefs about outcomes related to screening (*behavioral beliefs*); perceptions about important others' approval of engaging in screening (*normative beliefs*); and perceptions about one's ability to overcome barriers to engage in screening (*control beliefs*). *Social factors* include social support, norms, and instrumental support in overcoming barriers to screening. *Environmental factors* include provider recommendations for screening (e.g., routine, standard care recommendations), presence of healthcare processes that promote screening (e.g., systematic reminders for providers and patients to screen), and system-level requirements to enable access to screening, such as transportation to and from appointments.

2.3. Ethics

The study has been reviewed and approved by a Central IRB. All participants must provide informed consent to participate. Because this study is funded by Exact Sciences, the parent company for Cologuard, the only s-DNA FIT currently available, several strategies are being used to safeguard against potential influence and interference. First, the study is co-led by investigators at Mayo Clinic, University of Utah, and Fred Hutchinson Cancer Center. Second, data collection and monitoring are managed by third-party vendors, Signant Health and ICON, Plc. Patient participant surveys are be administered by Signant, stored on servers at Exact Sciences, and then sent directly to the statistical team at Fred Hutchinson Cancer Center. An independent data review committee, comprised of highly qualified scientists and managed by ICON, will review study and data transfer procedures, patient data collection, and evaluate risks for inappropriate data manipulation. Third, the study design, hypotheses, measures, outcomes, and analyses have been formulated a-priori and publicly disclosed (via ClinicalTrials.gov NCT05246839) prior to study initiation to ensure that the scientific process is transparent.

2.4. Setting

Up to 40 sites from every region of the United States sites are being recruited. Sites will include primary care and Obstetrician/Gynecology practices serving adult patients at academic health clinics, community-based practices, and federally qualified health clinics. Clinics are eligible if >25% of patients have never been screened or have been screened but are currently due for CRC screening per USPSTF screening guidelines and <80% of patients are white. Clinics will be geographically dispersed throughout the US and represent urban, suburban, and rural patient populations. Recruited sites contract with the study sponsor to cover personnel, administrative, and participant remuneration costs. Healthcare providers do not receive education about screening choices, nor are they given educational resources for their patients.

2.5. Eligibility

Inclusion and exclusion criteria for patient participation are listed in Table 2. The study is enrolling approximately 5280 participants, with equal numbers of participants who have never been screened for CRC (i. e., screening naïve) and those previously screened, but not currently adherent to USPTF guidelines. Patients are eligible to participate if they are ages 45 to 70 years, inclusive; have an upcoming primary care appointment; understand study procedures; can provide informed consent to participate in the study; and, authorize release of relevant protected health information. Although recommendations for average-risk screening include people ages 45–75, only those up to age 70 are eligible because by the end of the study period, those participants will reach 75 years. Patients are not eligible to participate if they have symptoms or signs that require immediate, or near-term referral for diagnostic or therapeutic colonoscopy, have a personal diagnosis or family history of conditions that put the participants at greater than average risk for CRC [32].

For provider and administrator surveys, providers at selected study sites who see adult patients are eligible. Healthcare administrators who are familiar with clinic CRC screening processes, quality improvement efforts, and/or planning or decision making about efforts to meet screening metrics are eligible.

2.6. Intervention development

Videos were professionally produced in English and Spanish in 2021–2022 for ACS. ACS received an educational grant from the study sponsor to produce the videos. The script for the ACS basic video was developed by the investigative team (JMG, LJFR, XZ) using ACS patient-facing educational materials that describe CRC screening and its possible benefits, as well as encourage CRC screening. The investigative team at Mayo Clinic drafted the informed choice video script based on the study's conceptual model (Fig. 1). A panel from Fight Colorectal Cancer, a national advocacy organization, reviewed and provided feedback on early drafts and choice messaging, and subsequently, the team made revisions. It The investigative team provided ACS with the revised scripts. ACS reviewed scripts for balanced messaging and then shared the modified script with 13 patients (11 eligible for screening; 2 survivors) who provided feedback. ACS incorporated feedback on wording, set and acting directions, and animated visuals in the videos before video production.

The informed choice video addresses personal, cognitive, and environmental factors expected to influence intention to screen and screening behavior. Also included in the informed choice video are persuasive communication principles and strategies, such as vicarious learning, positive emotional appeals, relatable characters, trustworthy and expert information sources, emphasis on positive outcomes, and calls to action that encourage patient attention and improve persuasion and recall of key messages [33–36]. The informed choice video describes advantages and disadvantages of colonoscopy, FIT, and s-DNA FIT.

2.7. Interventions and usual care arms

Arm 1 (Usual care).—Participants randomized to Arm 1 are in the control condition. They receive usual care pertaining to CRC screening at their respective clinical site. Participants randomized into Arm 1 neither view the ACS basic video nor the informed

choice video. *Arm 2 (ACS basic video).* Participants randomized into Arm 2 view the ACS basic video in its entirety (4 min, 3 s) prior to initiating the index appointment with their provider. *Arm 3 (Basic video + informed choice).* Participants randomized into Arm 3 watch the ACS basic video and the informed choice video (12 min, 29 s) that describes three CRC screening modalities: colonoscopy, FIT, and s-DNA FIT. The order in which the modalities are presented is randomly assigned to each participant in Arm 3. Participants view the basic video + informed choice videos in their entirety prior to initiating the index appointment with their provider.

2.8. Enrollment

Study coordinators screen all upcoming appointments to assess patient eligibility. Potentially eligible patients are contacted by the study coordinator prior to the appointment to discuss the study and determine interest in participating. Eligible and willing patients are sent consent forms and baseline surveys prior to the appointment. Participant intervention assignment is concealed from the study coordinator at recruitment to reduce potential bias (concealed allocation). On-site study coordinators are in clinic to present any forms not completed prior to the appointment and to recruit potentially eligible patients who were not reached by phone prior to appointment. Informed consent is captured electronically prior to the index appointment or in clinic during the index appointment. Participants receive $25 remuneration after T0-T2 are completed and $25 after T3 is completed.

Participants may request to withdraw from the study at any time. They may also be withdrawn if investigators agree that withdrawal is in the participant's best interest or after review of record, determined not to meet eligibility criteria. Participants withdrawn from the study may not re-enroll; however, they may be replaced while enrollment into the study remains open.

2.9. Randomization

Participants are randomized in the clinic setting at the time of the index appointment using a computer-based block randomization method. Our protocol does not indicate that participants should be told to which arm they have been assigned, but they may deduce their assignment based on whether or not they watch videos or the content of the videos. Randomization is applied at the household level to avoid cross-contamination due to members in the same household (e.g., spouses) randomized to different study arms. Regardless of when they are enrolled, those in the same household are assigned to the same arm. Screening status is collected prior to randomization and the randomization algorithm includes a cohort cap for screening naïve and previously screened participants. Once the cohort cap for a screening category has been met, no additional participants will be randomized to that intervention arm.

Neither participation nor study arm allocation is revealed to participants' providers prior to the index appointment; however, because participants are encouraged in the videos to talk to their provider about screening choices, it is possible that the provider may deduce the participant's allocation.

2.10. Data collection procedures

Study-related activities include completing 4 surveys (T0-T3) and privately viewing up to two videos at the time of the index appointment (Fig. 2). Participants are contacted annually via email (T4-T9) to capture health screening activity and determine if they have changed providers. The expected duration of participation is approximately 6 years. This allows for observation of adherence to six episodes of FIT, two episodes of s-DNA-FIT, and one episode of colonoscopy.

After providing consent, participants complete a Time 0 (T0) electronic web-based survey either at home or on a tablet in the clinic before their index appointment. Completion of T0 survey is required for randomization into a study arm. The T0 survey includes questions on participant (e.g., demographics, disabilities, quality of life) and environmental (e.g., healthcare access, and social support) factors, on awareness of CRC screening options and initial (if any) preference for screening and intention to screen.

At the index appointment, participants in all arms complete the T1 survey which includes one question on intention to screen for CRC and one on preference for screening modality. The T1 surveys are presented to participants on electronic tablets. Participants in Arm 1 complete the T1 survey after randomization and prior to the clinical encounter. Participants in Arms 2 and 3 complete T1 immediately following the intervention video(s) viewing, but prior to the beginning of the clinical encounter during the index appointment. Immediately following the index appointment, participants in all arms complete the T2 survey on study tablets. The T2 survey includes 8 questions, 6 which pertain to discussions and/or recommendations from the provider about CRC screening, one on intention to screen and one on preference for screening modality. One week following the index appointment, participants in all arms are sent the T3 survey. This survey includes questions on personal (e.g., CRC screening history), environmental (e.g., provider recommendations, trust in providers, medical care experiences, barriers to screening, such as costs) and cognitive factors (e.g., attitudes; normative, outcome, and control beliefs, self-efficacy). The remaining surveys (T4-T9) are sent at yearly intervals, beginning one year after the index appointment. Survey questions are about continuity of receiving care from the original provider/healthcare system and about general screening behaviors, including for CRC. Following T9, the study is complete for the participant. Fidelity and data reports on study randomization and data collection procedures are evaluated no less than quarterly by ICON.

Study coordinators extract eligibility and screening history data from participants' electronic medical records (EMR) prior to randomization, and then annually. Study coordinators use extracted data to complete an electronic Case Report Form (CRF) for each participant. If participants report a change in provider on any of the T4-T9 surveys, the participant's self-reported screening data from corresponding surveys are used to track screening and diagnostic outcomes after reported change.

Healthcare providers and health administrators at study sites are also surveyed

2.11. Outcomes

Table 3 presents all primary, secondary, and exploratory outcomes, variables, data sources, and samples from which the outcome or explanatory variables are assessed. The primary outcome is PTC from the index appointment to 1, 3, and 6 years [37,38]. Using this approach allows us to determine the intervention effect on CRC screening adherence over time. PTC is compared across the three study arms for each of the three time points, and for each of two screening status groups (i.e., screening naïve and previously screened), separately for 1-year outcomes and combined for 3- and 6-year outcomes. In addition to PTC by study arm, analyses consider gender, race/ethnicity, age, health insurance type, geographic location (urban vs rural), SES, and education level.

2.12. Data analyses

Shown in Table 4, the study aims to recruit 880 participants per arm and screening status group, for a total study sample size of 5280. When accrued, the study achieves at least 90% power to detect 10% differences for each of twelve planned comparisons using a two-sided type I error rate of 0.05(e.g., 50% vs. 60% of time covered 1 year after the index appointment for screening naïve participants in the ACS basic video arm compared to naïve participants in the basic + informed choice video arm). This 10% intervention effect size is clinically significant and thus this study has a strong chance of yielding significant results for such clinically meaningful effect sizes.

Since preliminary data on the distribution of PTC, household sizes, and within household correlation are not available, we took a conservative approach to calculate statistical power and sample size by dichotomizing the outcome, and assuming all households have two participants, and using an intraclass correlation of 0.5. The calculation [39]accounted for within household correlation with a variance inflation factor, VIF = 1 + (n-1)*r, where n is cluster size ($n = 2$) and r is intraclass correlation ($r = 0.5$) [39].

The statistical power and sample size determination assume a < 15% loss of follow up for the 1-year PTC outcome. The sample size determination considers that for the evaluation of 3-year and 6-year primary outcomes, the two screening history groups will be combined, as many participants in screening naïve group are no longer screening naïve after their initial screening. Because of this, the statistical power for the 3- and 6-year outcomes would only be compromised, i.e., <90% as designed, when the loss-to-follow up exceeds 50%. We have designed the follow-up EHR data capture, participant tracking and survey methods in ways to minimize the likelihood of this.

The PTC is calculated as the proportion of time adherent to screening guidelines between a participant's index appointment and the outcome dates (1, 3, 6 years), regardless of other factors, such as delays in scheduling. Duration of adherence depends on screening modality choice: 1 year for FIT, 3 years for s-DNA FIT, and 10 years for colonoscopy. For example, if a participant has a colonoscopy one month after the index appointment, that participant is 91.7% adherent (11/12 months) for the 1-year outcome. Likewise, if a participant has an index appointment and 3 months later completes s-DNA FIT with a negative result and then completes another s-DNA FIT at 45 months, the participant is 75% adherent for 1-year

outcomes (9/12 months), 91.7% adherent for 3-year outcomes (33/36 months) and 87.5% adherent for 6-year outcomes (63/72 months). A positive screening test stops the counting of PTC. For example, if this same participant's first s-DNA FIT result is positive, the data contribute to 1-year and 3-year outcomes, but the data do not contribute to the 6-year outcome.

An intention to treat approach is used for all analyses. Since the normality assumption of the distributions of outcomes is unlikely to hold due to mixture of four modalities (no screening, FIT, s-DNA FIT, colonoscopy) and responses from the same household being correlated, bootstrap methods are used to make inferences about the distributions of outcomes. Within each arm, 10,000 bootstrap samples, with household as resampling unit, are used to obtain the distribution of the mean difference between two arms, 95% confidence intervals and two-sided p-values [40]. If the mean difference is statistically significant, the means of PTC for each screening modality and the proportion of participants using each modality in the two arms are compared. This approach allows us to test whether improvements in adherence in Arm 3 compared to Arm 1 are due to an increasing proportion of participants using s-DNA FIT. Since there are 12 a-priori comparisons, yet each asks a specific question, multiple comparison adjustments are not planned. Plans include reporting results from all 12 comparisons regardless their statistical significance.

Recruitment and intervention activities are expected to be completed before the data are ready to analyze the 1-year endpoint. No interim analyses will be conducted before the 1-year endpoint. Regardless of findings at 1-year, we will continue, per protocol, with analysis of 3-year and 6-year endpoints and will also continue with all secondary outcome analyses.

Missing data on surveys are minimized because data are collected electronically, and answers are required. If medical record data are not available after the first year, we plan to use self-reported data on CRC screening and modality from the T4-T9 surveys. The concordance of the study primary outcome between these two sources will be compared for all participants, if available. If there is a bias in self-report (e.g., 10% of self-reports overreport the completed number of FITs by an average of 5%), an adjustment will be made for the self-reported study outcome according to the distribution of non-concordance.

For the provider and administrative surveys, we will use site-level factors as time-varying covariates in GEE models with potential interactions with treatment assignment.

3. Discussion

Low-cost, accessible, and innovative strategies are needed to inform, motivate, and facilitate screening among the nearly 30% of US adults between the ages of 50–75 years old who have never been screened or are not current with recommended CRC screening as well as those ages 45–49 who are now encouraged to screen. Provider recommendation is a strong predictor of screening completion, yet previous research has counting of PTC. For example, if this same participant's first s-DNA FIT result is positive, the data contribute to 1-year and 3-year outcomes, but the data do not contribute to the 6-year outcome. shown that when

providers restrict recommendations to only colonoscopy, uptake rates are lower than when patients are provided choices [17].

Using videos to present available CRC screening options assures consistency in information and reduces barriers due to health literacy [41]. Although the videos are designed to be implemented in a clinical environment and integrated into clinical processes prior to a healthcare appointment, they are also appropriate for broader health education. The basic English and Spanish videos are currently available from ACS (www.cancer.org). The informed choice videos will be available from ACS after the study is complete. In contrast to previous studies that have mailed videos prior to clinical appointments [42], our study requires participants to view the video in the clinic immediately preceding the clinical encounters and viewing software allows verification that the entire video was viewed. With research showing that CRC screening rates are higher in clinics with visit-based strategies that support screening [43], this study, if effective at improving PTC, can easily be scalable to busy clinical settings without adding significant costs.

This study's strengths include comparisons of s-DNA FIT to colonoscopy and FIT. Since s-DNA FIT is a relatively new modality, it has not been included in the volume of studies that have compared FIT and colonoscopy on screening preferences and completion. Thus, our study will provide data on how informed choice about three modalities affects PTC. With 1-, 3-, and 6-year endpoints, the study will advance scientific understanding of screening hesitancy and programmatic adherence, including intermittent and continuous adherence. The design includes an equal number of participants naïve to CRC screening and participants who are not CRC guideline adherent at study initiation, thus addressing limitations in previous studies that have targeted patients regardless of screening status [44]. Having both screening naïve and previously screened participants also permits examination of the differential impact of the video interventions on each group and identification of unique mediators and moderators of adherence by group. This study also includes patients ages 45–49 for whom little data on screening preferences exists. The large sample is drawn from geographically and socioculturally diverse communities and diverse clinical settings, providing much needed data on the impact of informed choice on participants who have historically had lower screening rates and where disparities in CRC mortality persist.

The study team also recognizes potential challenges. Because it is industry-funded, the study team, comprised of partnerships across academic institutions, has developed multiple safeguards to reduce bias, including independent reviewers of study processes, data management by a third-party vendor, public disclosure of the a-priori analysis plan, and registration of the study protocol prior to study initiation. Methodological challenges include the length of participant follow-up which could result in loss-to-follow-up. Annual follow-up surveys help address this challenge.

4. Conclusion

This three-arm randomized controlled trial is testing the impact of a video to inform patients of CRC screening options immediately preceding a healthcare encounter on CRC screening. With a large, diverse sample, this study addresses theoretical and methodological limitations

from previous studies and, if effective, will provide an easy, cost-effective, and scalable strategy to encourage CRC screening.

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Declaration of Competing Interest

All authors have an investigator services agreement between their respective institutions and Exact Sciences to support their effort.

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Data availability

No data was used for the research described in the article.

Abbreviations:

CRC	colorectal cancer
FIT	fecal immunochemical test
s-DNA FIT	stool DNA fecal immunochemical test
PTC	percentage of time covered
ACS	American Cancer Society
SES	Socioeconomic status
USPSTF	United States Preventive Services Task Force
TPB	Theory of Planned Behavior

SCT	Social Cognitive Theory
QOL	Quality of Life
EMR	Electronic medical record
CRF	Case report form

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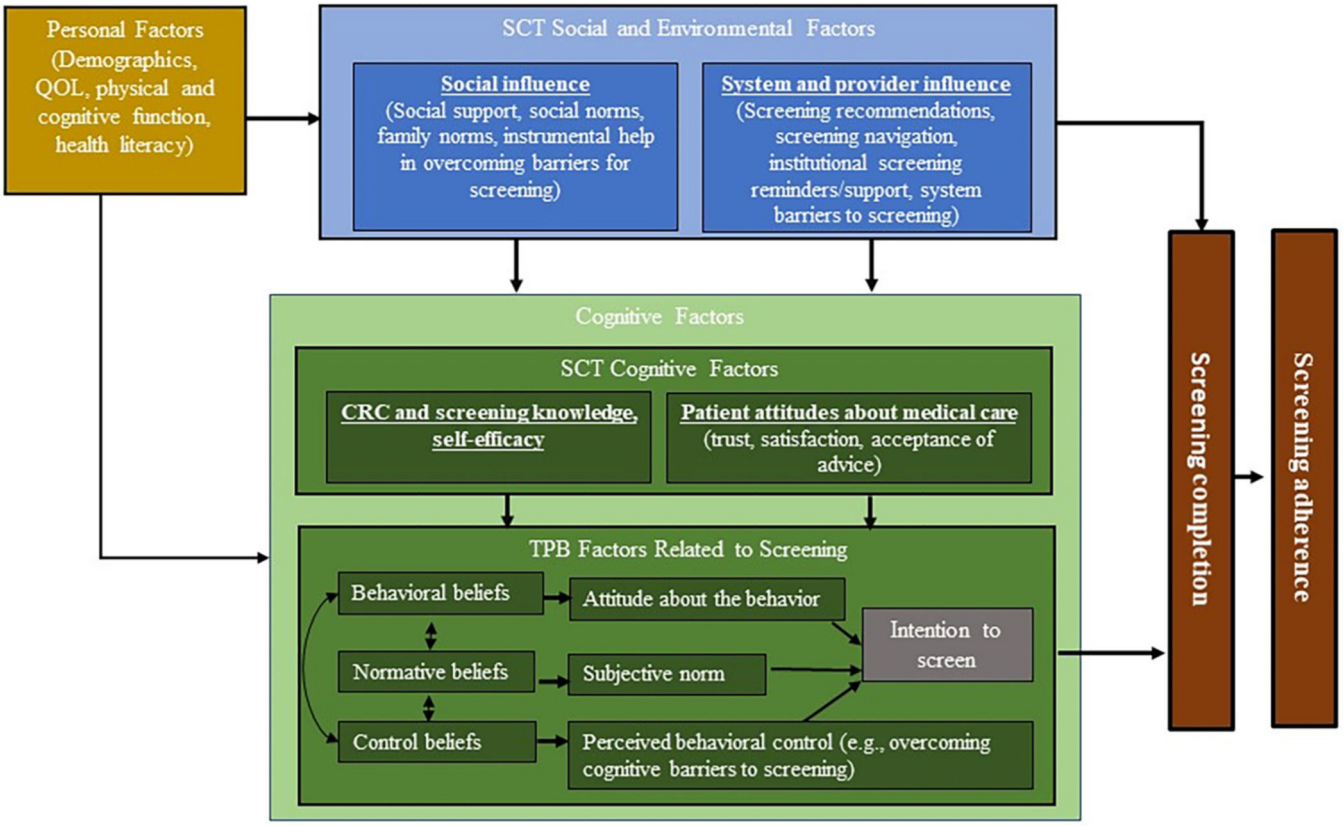

Fig. 1.
COMPASS conceptual model.

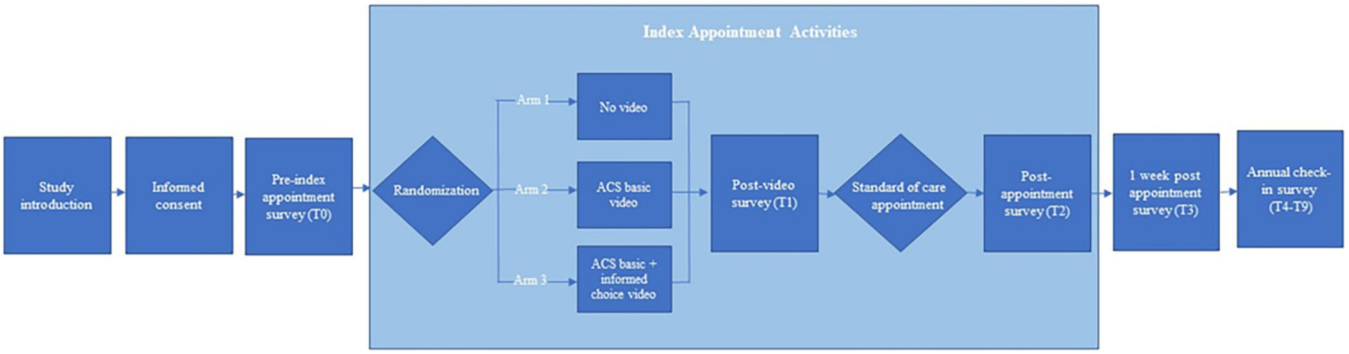

Fig. 2.
COMPASS study timeline.

Table 1

COMPASS trial A-priori outcomes and hypotheses.

Outcome	Hypothesis
Primary-% of time adherent	1. Arm 2 has higher PTC to CRC guidelines at 1 year than Arm 1 among screening naïve 2. Arm 2 has higher PTC to CRC guidelines at 1 year than Arm 1 among previously screened 3. Arm 3 has higher PTC to CRC guidelines at 1 year than Arm 1 among screening naïve 4. Arm 3 has higher PTC for CRC guidelines at 1 year than Arm 1 among previously screened 5. Arm 3 has higher PTC for CRC guidelines at 1 year than Arm 2 among screening naïve 6. Arm 3 has higher PTC for CRC guidelines at 1 year than Arm 2 among previously screened 7. Arm 2 has higher PTC for CRC guidelines than Arm 1 at 3 years 8. Arm 3 has higher PTC for CRC guidelines than Arm 1 at 3 years 9. Arm 3 has higher PTC for CRC guidelines than Arm 2 at 3 years 10. Arm 2 has higher PTC for CRC guidelines than Arm 1 at 6 years 11. Arm 3 has higher PTC for CRC guidelines than Arm 1 at 6 years 12. Arm 3 has higher PTC for CRC guidelines than Arm 2 at 6 years
Secondary-Intention	1. Between T0 and T1, screening naïve and previously screened in Arm 2 have greater changes in intention to screen for CRC than the screening naïve and previously screened in Arm 1 2. Between T0 and T1, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 1 3. Between T0 and T1, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 2 4. Between T1 and T2, screening naïve and previously screened in Arm 2 have greater change in intention to screen for CRC than the screening naïve in Arm 1 5. Between T1 and T2, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC screening naïve and previously screened in Arm 1 6. Between T1 and T2, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 2 7. Between T2 and T3, screening naïve and previously screened in Arm 2 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 1 8. Between T2 and T3, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 1 9. Between T2 and T3, screening naïve and previously screened in Arm 3 have greater change in intention to screen for CRC than screening naïve and previously screened in Arm 2
Secondary-Preferences	10. Between T0 and T1, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm 1 11. Between T0 and T1, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm 2 12. Between T1 and T2, screening naïve and previously screened in Arm 2 have greater change in CRC screening modality preference than the screening naïve in Arm 1 13. Between T1 and T2, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference screening naïve and previously screened in Arm 1 14. Between T1 and T2, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm 2 15. Between T2 and T3, screening naïve and previously screened in Arm 2 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm 1 16. Between T2 and T3, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm 1 17. Between T2 and T3, screening naïve and previously screened in Arm 3 have greater change in CRC screening modality preference than screening naïve and previously screened in Arm
Secondary-follow up colonoscopy rate	18. Among those a positive FIT or s-DNA FIT, those in Arm 2 has higher rates of follow-up colonoscopies than those in Arm 1 19. Among those a positive FIT or s-DNA FIT, those in Arm 3 has higher rates of follow-up colonoscopies than those in Arm 1 20. Among those a positive FIT or s-DNA FIT, those in Arm 3 has higher rates of follow-up colonoscopies than those in Arm 2
Secondary-colorectal neoplasias	21. Colorectal neoplasias at 1 year are associated with arm assignment, modality, history of screening and personal factors. 22. Colorectal neoplasias at 3 years are associated with arm assignment, modality, history of screening and personal factors. 23. Colorectal neoplasias at 6 years are associated with arm assignment, modality, history of screening and personal factors.
Secondary-longitudinal CRC incidence/stage of diagnosis/mortality	24. At 6 years, CRC incidence, CRC stage of diagnosis, and CRC-related mortality are associated with arm assignment, modality, history of screening and personal factors.
Exploratory-Concordance of	25. What is the concordance between CRC screening modality preference at T2 and modality at first completed CRC screening?

Outcome	Hypothesis
preference and actual modality	
Exploratory-Provider, system and site-level factors associated with % of time adherent	26. What provider, system and site-level factors are associated with participant % of time adherent at 1 year, 3 years and 6 years?
Exploratory-Discordance between screening and follow up tests	27. For those with a follow-up colonos copy after a positive FIT, what is the incidence rate of no colorectal neoplasia?
	28. For those with a follow-up colonoscopy after a positive s-DNA FIT, what is the incidence rate of no colorectal neoplasia?
Incidence of incidental cancer dx	29. For those with a negative follow-up colonoscopy after a positive FIT, what is the incidence rate of any kind of cancer?
	30. For those with a negative follow-up colonoscopy after a positive s-DNA FIT, what is the incidence rate of any kind of cancer?

Table 2

COMPASS trial inclusion and exclusion criteria for study participation.

Inclusion Criteria
1. Participant is 45 to 70 years of age, inclusive.
2. Participant presents for a primary care appointment for healthcare maintenance.
3. Participant understands the study procedures and can provide informed consent to participate in the study and authorization for release of relevant protected health information (PHI) to the study Investigator.
Exclusion Criteria
1. Participant has symptoms or signs that require immediate, or near term, referral for diagnostic or therapeutic colonoscopy.
2. Participant has a personal history of CRC or colonic adenomatous or sessile serrated polyps.
3. Participant has a personal history of inflammatory bowel disease.
4. Participant has a family history of CRC in at least one first- or second-degree relative diagnosed prior to age 60 years and/or at least 2 first-degree relatives diagnosed with CRC at any age.
5. Participant has a personal diagnosis or family history of any of the following conditions:
a. Familial adenomatous polyposis (also referred to as “FAP”, including attenuated FAP and Gardner’s syndrome),
b. Hereditary non-polyposis CRC syndrome (also referred to as “HNPCC” or “Lynch Syndrome”),
c. Other hereditary cancer syndromes including but are not limited to Peutz–Jeghers Syndrome, MYH-Associated Polyposis (MAP), Turcot’s (or Crail’s) Syndrome, Cowden’s Syndrome, Juvenile Polyposis, Neurofibromatosis, or Familial Hyperplastic Polyposis.
6. Participant has a diagnosis of Cronkhite-Canada Syndrome
7. Participant is current with CRC screening, including gFOBT or FIT within the preceding 12 months, s-DNA FIT within the preceding 3 years, flexible sigmoidoscopy, or CT colonography within the preceding 5 years, or colonoscopy within the preceding 10 years. Participants can be enrolled up to 3 months prior to screening due date.
8. Participant has any condition that in the opinion of the Investigators should preclude participation in the study, including comorbid illnesses precluding endoscopic evaluation or that limit life expectancy to <10 years.

Table 3

COMPASS trial outcomes and explanatory variables.

Outcomes	Data Source	Sample
Primary Outcomes		
PTC–CRC guidelines − 1 year	EMR/self-report	Total; screening naïve; previously screened
PTC–CRC guidelines − 3 years	EMR/self-report	Total
PTC-CRC guidelines − 6 years	EMR/self-report	Total
Secondary Outcomes		
Change in intention to screen; T0 to T1	Self-report	Total; screening naïve; previously screened
Change in intention to screen; T1 to T2	Self-report	Total; screening naïve; previously screened
Change in intention to screen; T2 to T3	Self-report	Total; screening naïve; previously screened
Change in preferred screening modality to screen; T0 to T1	Self-report	Total; screening naïve; previously screened
Change in preferred screening modality to screen; T1 to T2	Self-report	Total; screening naïve; previously screened
Change in preferred screening modality to screen; T2 to T3	Self-report	Total; screening naïve; previously screened
Follow-up colonoscopy	EMR	Positive FIT or s-DNA-FIT
Colorectal neoplasias-1 year**	EMR	Screened by: FIT; s-DNA-FIT; colonoscopy
Colorectal neoplasia-3 years**	EMR	Screened by: FIT; s-DNA-FIT; colonoscopy
Colorectal neoplasias-6 years**	EMR	Screened by: FIT; s-DNA-FIT; colonoscopy
CRC incidence (index appointment to 6 years)	EMR/self-report	Total
Mortality (index appointment to 6 years)	EMR	Total
Exploratory Outcomes		
Concordance of screening modality preference and completed screening modality	EMR/self-report	Total
% of time covered (PTC)	EMR/staff report	Staff and management reports
Any cancer incidence (index appointment to 6 years)	EMR	Participants with discordant screening and follow-up findings.
Explanatory factors (Personal)	**Data Source**	**Sample**
Demographic		
Sociodemographics (Age, race/ethnicity, gender identity, marital status, education, household income)	Self-report	Total
CRC history	EMR/self-report	Total
CRC screening history	EMR/self-report	Total
Disability status	Self-report	Total
Quality of Life	Self-report	Total
Health literacy	Self-report	Total
Health insurance coverage	EMR/self-report	Total
Environmental		
Healthcare access	Self-report	Total
Social support	Self-report	Total
Provider recommendation	Self-report	Total
Barriers for screening (e.g., cost, time)	Self-report	Total

Outcomes	Data Source	Sample
Trust in providers	Self-report	Total
Cognitive		
Knowledge	Self-report	Total
Behavioral beliefs	Self-report	Total
Control beliefs (self-efficacy, cognitive barriers to screen)	Self-report	Total
Normative beliefs	Self-report	Total
Providers and Management		
Provider attitudes	Self-report	Providers
Practice changes	Self-report	
		Providers and management
Clinical support for screening	Self-report	Providers and management
Change in clinic navigation for screening	Self-report	Providers and management

Table 4

COMPASS trial estimated sample sizes.

	Arm 1	Arm 2	Arm 3	Total
Screening naïve	880	880	880	2640
Previously screened	880	880	880	2640
Total	1760	1760	1760	5280