BMJ Open

Randomised trial to evaluate the effectiveness and impact of offering postvisit decision support and assistance in obtaining physician-recommended colorectal cancer screening: the e-assist: Colon Health study—a protocol study

Jennifer Elston Lafata,[1,2,3] Yongyun Shin,[4] Susan A Flocke,[5,6] Sarah T Hawley,[7] Resa M Jones,[8,9] Ken Resnicow,[10] Michelle Schreiber,[3] Deirdre A Shires,[11] Shin-Ping Tu[12,13]

To cite: Lafata JE, Shin Y, Flocke SA, *et al*. Randomised trial to evaluate the effectiveness and impact of offering postvisit decision support and assistance in obtaining physician-recommended colorectal cancer screening: the e-assist: Colon Health study—a protocol study. *BMJ Open* 2019;**9**:e023986. doi:10.1136/bmjopen-2018-023986

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-023986).

Received 21 May 2018
Revised 14 August 2018
Accepted 18 October 2018

For numbered affiliations see end of article.

Correspondence to
Dr Jennifer Elston Lafata; jel@email.unc.edu

ABSTRACT

Introduction How to provide practice-integrated decision support to patients remains a challenge. We are testing the effectiveness of a practice-integrated programme targeting patients with a physician recommendation for colorectal cancer (CRC) screening.

Methods and analysis In partnership with healthcare teams, we developed 'e-assist: Colon Health', a patient-targeted, postvisit CRC screening decision support programme. The programme is housed within an electronic health record (EHR)-embedded patient portal. It leverages a physician screening recommendation as the cue to action and uses the portal to enrol and intervene with patients. Programme content complements patient–physician discussions by encouraging screening, addressing common questions and assisting with barrier removal. For evaluation, we are using a randomised trial in which patients are randomised to receive e-assist: Colon Health or one of two controls (usual care plus or usual care). Trial participants are average-risk, aged 50–75 years, due for CRC screening and received a physician order for stool testing or colonoscopy. Effectiveness will be evaluated by comparing screening use, as documented in the EHR, between trial enrollees in the e-assist: Colon Health and usual care plus (CRC screening information receipt) groups. Secondary outcomes include patient-perceived benefits of, barriers to and support for CRC screening and patient-reported CRC screening intent. The usual care group will be used to estimate screening use without intervention and programme impact at the population level. Differences in outcomes by study arm will be estimated with hierarchical logit models where patients are nested within physicians.

Ethics and dissemination All trial aspects have been approved by the Institutional Review Board of the health system in which the trial is being conducted. We will disseminate findings in diverse scientific venues and will target clinical and quality improvement audiences via other venues. The intervention could serve as a model for filling the gap between physician recommendations and patient action.

Trial registration number NCT02798224; Pre-results.

Strengths and limitations of this study

- ► Trial addresses how electronic health record (EHR)-embedded, online decision support and assistance can be used following patients' receipt of physician order for colorectal cancer (CRC) screening.
- ► Use of EHR-embedded patient portal to enrol patients and deliver intervention facilitates practice integration and provides efficient and sustainable platform for intervention.
- ► Programme facilitates informed decision making and addresses common barriers to and questions regarding CRC screening, thereby filling known gaps in office visit discussions.
- ► Enrolling and intervening with patients via the patient portal limits the programme's reach to those already engaged with portal technology.
- ► Study findings may be limited in that they may not generalise to other settings.

INTRODUCTION

Despite the availability of multiple effective colorectal cancer (CRC) screening tests, CRC screening remains underused relative to other cancer screening tests.[1] We have found that a driving factor behind this underutilisation for insured individuals is the gap that exists between physician recommendation and patient receipt of care. We previously found

that while the overwhelming majority (93%) of insured people due for CRC screening when visiting a physician office received a recommendation for screening, only 54% were screened in the following year.[2] Despite the known importance of physician recommendations to CRC screening use,[3 4] the gap between recommendation and screening use, in part, may be explained by the poor quality of typical patient–physician CRC screening discussions that have been shown to fall short of recommended decision-making processes and omit addressing common patient questions and CRC screening barriers.[3 5 6] To address these shortfalls, and close the gap between physician recommendation and care receipt, interventions are needed that encourage patient follow through, address lingering patient questions and assist with barrier removal following a physician recommendation for screening.

How to offer such decision support and assistance to patients in a way that is practice integrated remains a challenge. Individual health navigators hold promise, especially for low literacy patients, but costs associated with such programmes limit scalability.[7 8] Patient reminders and the removal of structural barriers can increase screening use, but these techniques leave many unscreened and are disconnected from physician recommendations and other existing clinic processes.[7 9–19] Similarly, traditional decision aids provided before an office visit often result in improved patient knowledge, but limited (if any) changes in screening behaviours and have proven difficult to integrate within practice.[20–23] The effectiveness of such previously tested CRC screening programmes may be limited by a combination of factors. These include their failure to be practice integrated and thus capitalise on the powerful patient–physician relationship and cue to action that exists once a physician recommends CRC screening, and the missed opportunity to intervene *after* an office visit in which CRC has been recommended with programme content that is complementary to typical office-based CRC screening discussions.

By leveraging the platform of an online patient portal that is embedded within the electronic health record (EHR), we have developed a practice-integrated, patient-targeted CRC screening programme, e-assist: Colon Health. The programme is delivered to patients via an EHR-embedded patient portal after an office visit in which CRC screening has been recommended, thereby leveraging physician recommendations as a cue to action. Programme content reinforces screening benefits and addresses typical patient questions and the personal and structural barriers faced once a physician recommendation has been received. We are evaluating e-assist: Colon Health using a practice-embedded trial in which patients are randomised to receive e-assist: Colon Health or one of two control arms (usual care plus or usual care).

Aims and hypotheses

The primary outcome of interest for the randomised trial is receipt of EHR-documented CRC screening within 12 months of physician recommendation. The overall aims of the evaluation include:

Aim 1: to compare screening use, intent to screen and patient perceptions among trial enrollees receiving e-assist: Colon Health and usual care plus.

H1: a larger proportion of trial enrollees receiving e-assist: Colon Health, compared with trial enrollees receiving usual care plus, will be screened for CRC within 12 months of receiving the physician recommendation.

H2: a larger proportion of trial enrollees receiving e-assist: Colon Health, compared with enrollees receiving usual care plus, will report intending to be screened at the time of the follow-up survey.

H3: trial enrollees receiving e-assist: Colon Health will perceive more benefits from CRC screening, more screening support and fewer CRC screening barriers at the time of the follow-up survey as compared with trial enrollees receiving usual care plus.

Aim 2: to evaluate whether the effectiveness of e-assist: Colon Health is moderated by factors including patient health literacy, decision-making preference and CRC screening decision stage as reported by trial enrollees at baseline.

H4: the effectiveness of e-assist: Colon Health will be greater among patients with low health literacy (compared with those with high health literacy), a preference for less directed decision making (compared with those with a preference for directed decision making) and a low decision stage (compared with those with a higher decision stage).

Aim 3: to characterise the impact of e-assist: Colon Health at a primary care population level by describing the ability of the programme to reach the target population and by comparing CRC screening use across the three study arms.

METHODS

Conceptual framework

Intervention and trial design are guided by the Health Belief Model (HBM),[24] the Precaution Adoption Process Model and Self-Determination Theory.[25–28] The HBM suggests that people's use of preventive services is explained by their perceived threat of disease, benefits of the service, barriers to and self-efficacy for obtaining screening. The model also acknowledges the need for a stimulus, or cue to action, to trigger the behaviour. The HBM provides overarching guidance for intervention design (eg, provision of information regarding the risks and consequences of CRC, and the benefits of screening; offering assistance overcoming barriers to screening; and addressing structural barriers to completing screening by providing direct access to stool testing and assistance with completing screening) as well as the impetus for targeting patients immediately following a primary care visit with an order for CRC screening (ie, an external cue to action that has occurred within established clinic processes). The HBM, however, does not provide guidance on how to personalise health communications and other intervention components to maximise message salience and

accompanying action. The Precaution Adoption Process Model provides this guidance by building on the core elements of the HBM and considering how a person comes to decisions to take action.[26] Specifically, the individual's readiness to engage in the healthful behaviour is based on their 'decision stage'. The premise behind the model is that different factors influence different stage transitions and that messages can be strategically designed to move individuals through the stages.[29 30] For example, the e-assist: Colon Health programme offers patients who indicate they are not ready to be screened suggestions for how to overcome common personal barriers to screening. Likewise, patients who indicate they are undecided about how to be screened are provided with information about the pros and cons of different test options, while those indicating they are ready to be screened are provided with tips for completing their preferred screening test and assistance removing structural barriers that may arise. Finally, we use principles from Self-Determination Theory to guide the tone of the written messages and ensure they are autonomy supporting[28] and are not overly directive or controlling. For example, the programme provides information on other types of CRC screening tests only to those who express an interest in this information and then emphasises that modality choice is up to the patient.

Study setting

The trial is being conducted within the primary care practice of an integrated health system. The practice's 33 primary care clinics are located throughout the city of Detroit and the surrounding suburban tricounty area. Clinics are staffed by approximately 150 salaried, adult primary care (ie, general internal medicine and family medicine) physicians. The health system uses a commercial EHR that includes an embedded patient portal.[31]

Patient and public involvement

The design of the programme and its integration with clinic workflow and practice were achieved via continual partnerships with care delivery and support teams. The user-centred design was used to ensure programme acceptability, scalability and sustainability. Patient input via focus groups, in-depth interviews and beta testing was used to develop the content of the e-assist: Colon Health programme.[32]

Study design

We are evaluating the e-assist: Colon Health programme using a three-arm, randomised trial. The trial is pragmatic and practice embedded, in that it uses available EHR data to identify, recruit and follow-up eligible patients.[33 34] By embedding these processes within the health system's infrastructure, we are able to invite a broad, generalisable group of patients and to do so in an efficient and sustainable way should the intervention be found effective under such 'real world' conditions.

To be consistent with the health system's preventive health practices, the inclusion and exclusion criteria for the trial was guided by the US Preventive Services Task Force guidelines for CRC screening.[35] As such, average-risk patients, aged 50–75 years, due for CRC screening were randomised to receive: (1) an online patient portal message with links to the interactive e-assist: Colon Health programme (experimental treatment); (2) an online patient portal message with links to Healthwise CRC and CRC screening educational material (usual care plus)[36]; or (3) usual care. For the effectiveness evaluation, we will use an intent-to-treat analysis among those consenting to study participation in the experimental treatment and usual care plus arms. Because an outreach communication specific to CRC screening following a physician recommendation may itself serve as a reminder and cue to action, we will use the third arm, for which there is no outreach communication or consent, to describe screening use in a population without any postvisit communication about CRC screening (usual care). The latter will be used to estimate programme impact at the population level. The evaluation framework is depicted in figure 1.

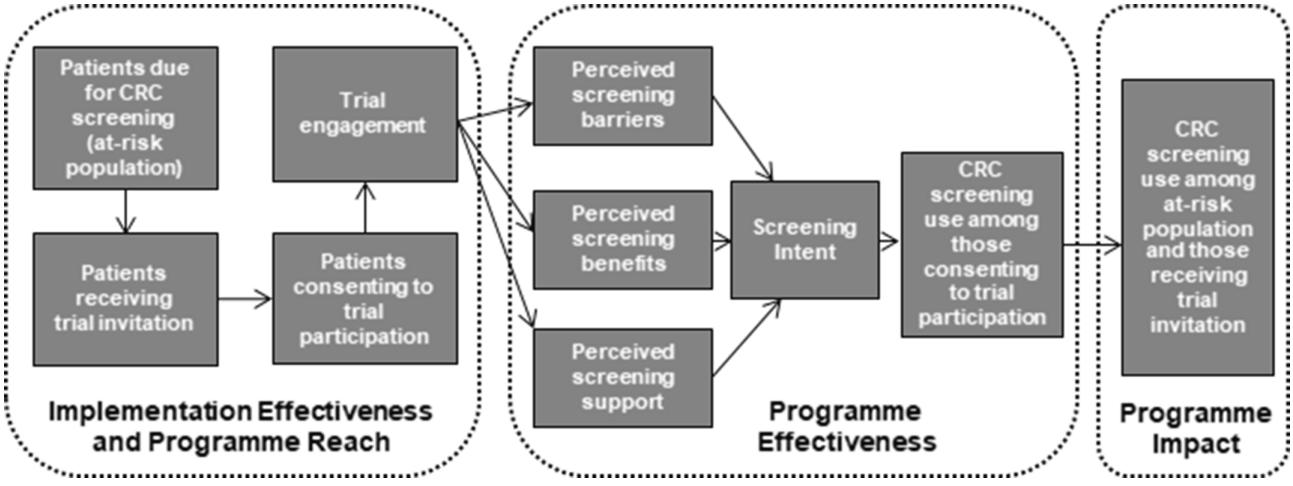

Figure 1 Evaluation framework. The figure provides an overview of the implementation and patient outcomes that are being assessed as part of the e-assist: Colon Health study. CRC, colorectal cancer.

Eligible patient identification and randomisation

Because of the desire to automate the workflow to recruit and intervene with patients and the inability to conduct randomisation within the EHR environment, we randomised all *potentially* trial-eligible patients before opening the trial to enrolment. This was done by using the EHR data repository to identify patients who would become study eligible if they were to receive a physician recommendation for CRC screening during the trial enrolment period. This list of *potentially* trial-eligible participants was generated by identifying average-risk men and women aged 50–75 years who were due for CRC screening as recommended by the US Preventive Services Task Force Guidelines,[35] had an activated online patient portal account and per administrative records were assigned to a primary care physician practising in one of the health system's 33 primary care clinics. Patients with EHR-documented colonoscopy in the past 10 years, sigmoidoscopy in the past 5 years or faecal occult blood test (FOBT) or faecal immunochemical test (FIT) in the past 12 months were excluded as were patients known to be above average risk for CRC (ie, those with a personal or family history of CRC, those with prior polyps or a history of inflammatory bowel disease, familial adenomatous polyposis or hereditary non-polyposis). Patients without an activated portal account and who were not aligned to a primary care physician were also excluded.

SAS software V.9.4 was used to randomly allocate potentially trial-eligible patients to the experimental treatment, usual care plus or usual care study arms. To ensure adequate sample size for the primary effectiveness analyses that will compare CRC screening use between the experimental treatment and the usual care plus groups (both of which require patient consent), we used a 2:2:1 ratio for randomisation. The pool of potentially eligible patients is scheduled to be updated approximately annually.

Study enrolment and baseline assessment

Figure 2 outlines the study processes from the identification of potentially trial-eligible patients through outcome measurement. As indicated in figure 2, while the trial is open for enrolment, the list of potentially trial-eligible participants (as identified above) is monitored electronically and continuously to identify those with an ambulatory care visit to a primary care physician that includes a referral for an open access colonoscopy, an order for stool testing (ie, FOBT or FIT), or both. Once a potentially eligible patient receives such an order, they become trial eligible. When the physician closes the encounter (ie, visit note within the EHR), if the patient has a preassigned randomisation code reflective of either the experimental treatment or usual care plus group, a secure message is sent automatically to the patient's online portal account inviting them to access an attached link that contains the decision support intervention appropriate to their study arm. Once an eligible patient opens the attached link, they are invited to participate in the study. Those continuing past an online consent page are considered enrolled in the trial. Trial enrolment is continuing until 900 patients are enrolled in each of the two study arms requiring consent (ie, the experimental treatment and usual care plus). At that time, any individual who was randomised to usual care and received a primary care physician order for CRC screening will be included in the usual care arm.

Figure 3 provides an overview of the study contact procedures by study arm as well as a brief synopsis of the intervention content (the latter of which is described in more detail below). For those in the experimental treatment and usual care plus groups, the online programmes contain a brief baseline questionnaire consisting of six measures that are being collected to assess balance between the experimental treatment and active comparison study arms and to enable the testing of patient-level factors that may moderate the effectiveness of e-assist: Colon Health. As indicated in table 1, these include previously validated measures of health literacy[37] and measures adapted for CRC screening such as perceived worry,[38] decision-making preference,[39–41] perceived susceptibility,[42 43] screening history[44] and CRC screening decision-making stage.[45] No similar assessment is given to the usual care group.

Outcome measures and follow-up assessment

As indicated in table 1, the primary effectiveness outcome for the trial is a binary variable reflecting CRC screening use in the 12-month period following the date of physician recommendation. Screening use is being determined by an EHR-documented occurrence of any of the following: colonoscopy, flexible sigmoidoscopy, FOBT, FIT or stool DNA testing. Patients for whom no indication of testing is identified in the EHR will be assumed not to have received screening.

Secondary outcomes include patient-perceived benefits of,[46] barriers to and support for CRC screening and patient-reported CRC screening intent (table 1).[47–49] The latter of which is obtained using a measure of behavioural intent adapted for CRC screening.[45] These secondary outcomes are being assessed via a telephone survey administered to participants enrolled in the experimental treatment and usual care plus arms only. The telephone survey is being administered 4–8 weeks following trial enrolment.

Experimental treatment: e-assist: Colon health

The e-assist: Colon Health programme is designed to serve as an online visit extender, filling known voids in typical office-based CRC screening decision-making processes and addressing key personal and structural barriers to CRC screening once a physician order has been placed. Programme content includes images, newly developed text and seven videos that were developed in the context of another NCI-funded trial (NCT01885351). After consenting to study participation and answering the baseline questionnaire, patients randomised to receive e-assist: Colon Health are able to view the content of the

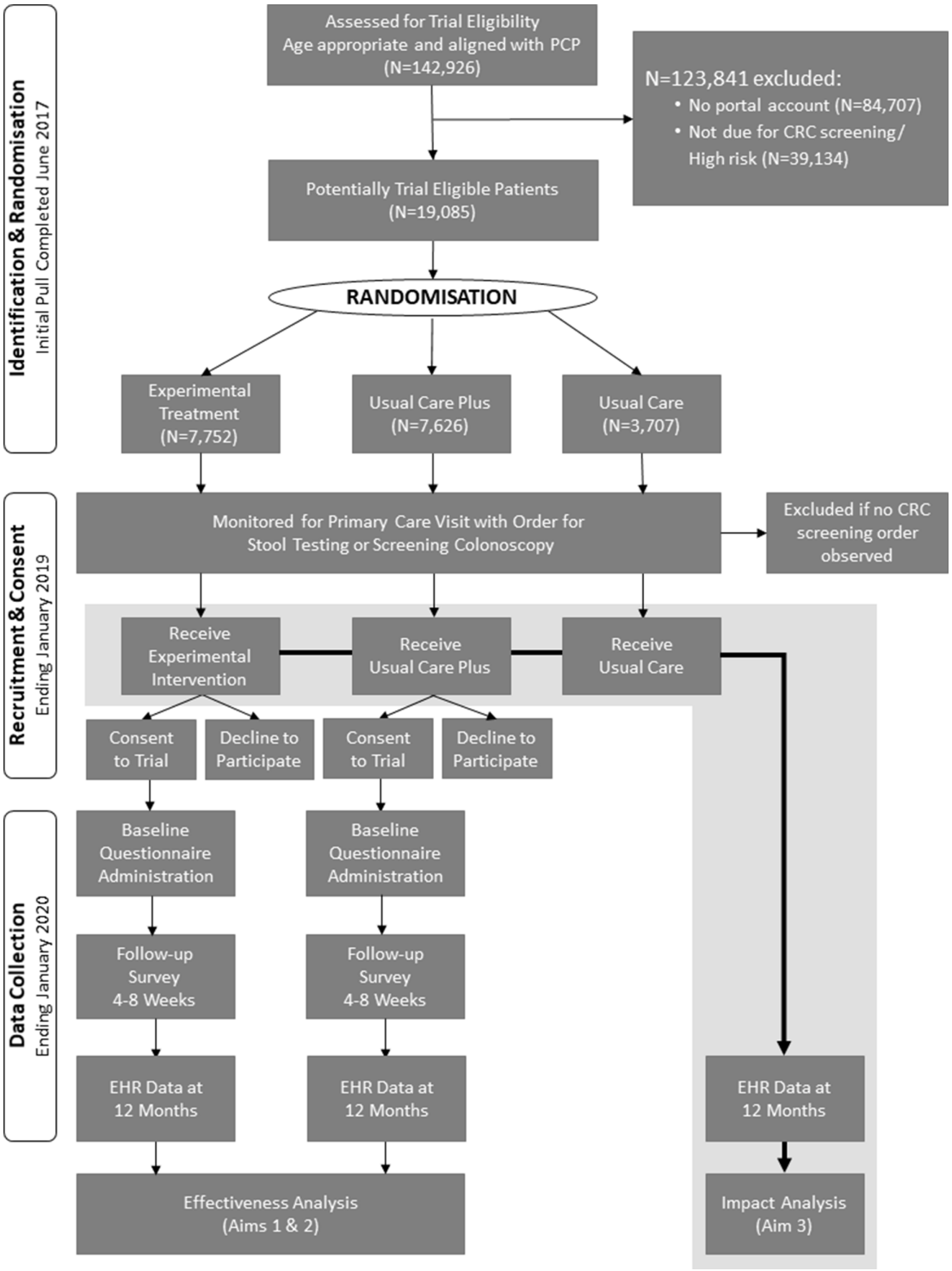

Figure 2 Study processes. The figure identifies how patients were identified, randomised, recruited and followed during the e-assist: Colon Health study. CRC, colorectal cancer; EHR, electronic health record.

initial module. There are five central components to the initial module: (1) messaging and a video to reiterate that CRC screening is recommended; (2) messaging to provide information on different screening modalities and associated benefits/risks; (3) a screening test option comparison to assist patients in determining their screening test preference; (4) messaging and videos addressing ways to overcome common personal barriers to screening; and (5) messaging to assist with completing screening once a decision to screen has been made. The majority (89%) of e-assist: Colon Health text content assesses at or below a sixth grade reading level with the remainder (11%) at a seventh grade level, as evaluated by the Flesch-Kincaid Grade Level test.[50]

Although messaging regarding the benefits of CRC screening and testing guidelines are seen by everyone,

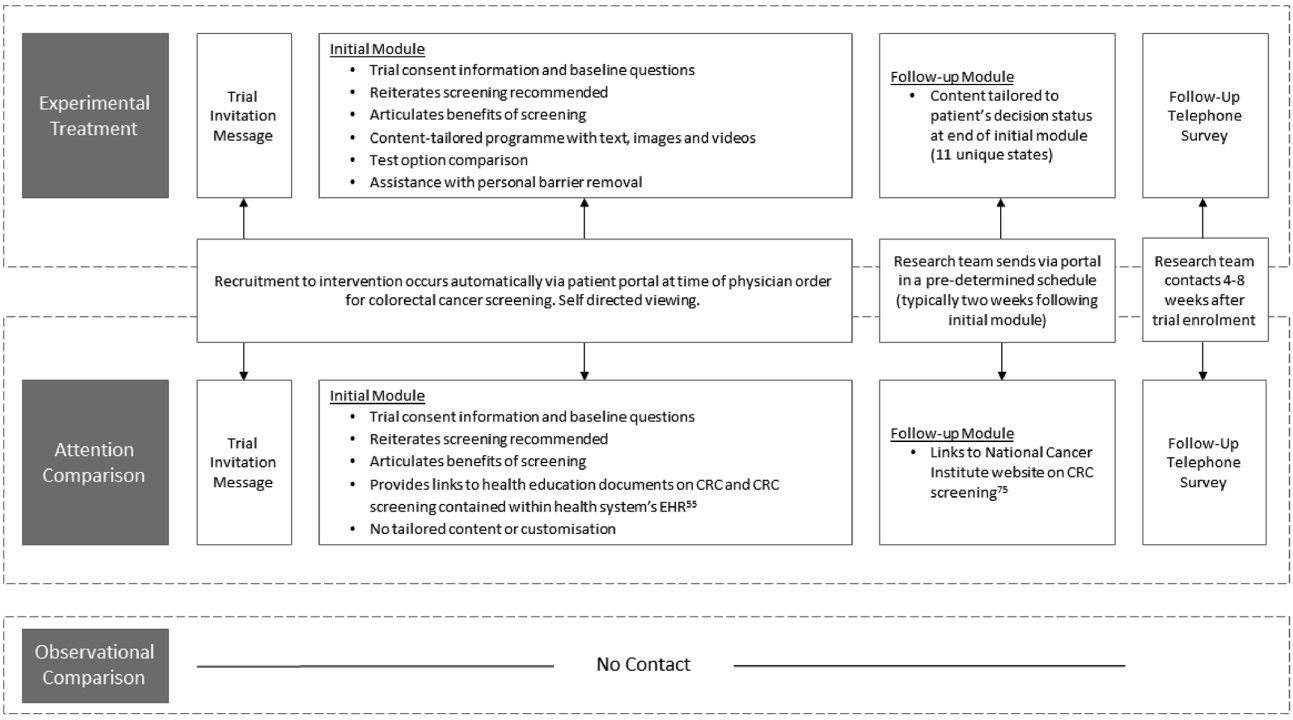

Figure 3 Intervention content and contact procedures by study arm. The figure summarises the points and content of participant contact during the e-assist: Colon Health study. CRC, colorectal cancer; EHR, electronic health record.

much of the programme's content is self-directed, enabling users to choose the material they want to view and the order in which they view it. Patients' readiness to screen along with their informational and CRC screening preferences are assessed through questions embedded throughout the programme. Participant responses are used to tailor the programme content seen to the participants' decision stage and preferences. The specific assistance a patient receives (eg, instructions for how to schedule a colonoscopy; instructions for how to prepare for a colonoscopy screening; requesting mailed delivery of stool test; or instructions for how to complete stool test) is similarly tailored based on the participant's responses to embedded questions. What participants view and the order in which they view it are being tracked as part of the implementation effectiveness component of

Table 1 Measures and schedule of measurement for trial participants receiving e-assist: Colon Health or the usual care plus

	Measure	Baseline questionnaire	Follow- up survey*	Medical record documented†
Primary outcome	CRC screening			X
Secondary outcomes	CRC screening intent[45]		X	
	Barriers to CRC screening[47 48]		X	
	CRC screening benefits[46]		X	
	Patient-provider supportive communication[49]		X	
Moderating factors	Health literacy[37]	X	X	
	CRC Decision Stage[45]		X	
	Decision-making preference[39–41]	X	X	
	Perceived worry[38]	X	X	
	CRC screening history[44]	X		
	Perceived CRC susceptibility[42 43]	X	X	

*Follow-up survey administered 4–8 weeks following for trial enrolment.
†CRC screening as indicated by receipt of colonoscopy, flexible sigmoidoscopy, faecal occult blood testing, faecal immunochemical testing or stool DNA testing within 12 months of physician recommendation for screening as documented in the electronic health record.
CRC, colorectal cancer.

the evaluation. Although participants can return to the initial module as often as they want until they submit it as completed, we anticipate most participants completing the initial module in one session that lasts between 8 min and 12 min, depending up information viewed.

Near the end of the initial module, a course of action is negotiated that is aligned with the patient's preferences and willingness to be screened. If a participant's responses indicate he or she is ready to be screened, the e-assist: Colon Health programme facilitates receipt of screening by assisting with the removal of structural barriers that may arise (eg, how to call the endoscopy nurse schedulers with questions). For participants expressing a desire to be screened using a test different from what their physician ordered, the programme assists in obtaining their desired CRC screening test by providing contact information for the central scheduling line or messaging the patient's physician directly.

Any participant that does not indicate they have completed CRC screening when they submit their initial module receives a follow-up module. Much of the content in this follow-up is similar to that available in the initial module although targeted based on the information and preferences shared via question responses within the initial module. For example, if during the first module a participant elected to send a secure message to their primary care physician requesting a stool test, the content in the follow-up module would confirm that the participant received the stool test and offer tips for completion. For patients that do not express a desire to be screened, the follow-up module presents information using a motivational counselling approach.[51] This approach is aimed at moving patients who are undecided or not considering screening towards a concrete decision. It does so by highlighting the personal relevance of screening, the risks of CRC and the benefits of screening, while identifying personally relevant barriers. There are a total of 11 different follow-up modules. As with the initial module, programme navigation within each of these modules is self-directed with participants' responses to embedded questions used to tailor the programme content seen. All follow-up modules are delivered 2 weeks after the initial module was submitted as completed, with the exception of those targeting participants who indicated they were not ready to be screened or those who abandoned the programme without submitting it. For the former, the follow-up module is sent 28 days later, while for the latter, 7 days later.

Usual care plus

Patients randomised to usual care plus receive the identical recruitment message as those in the experimental arm (figure 3). Also identical are the consent form page and introductory screens reiterating that CRC screening has been recommended for them and outlining the benefits of screening. In lieu of the interactive e-assist: Colon Health programme, individuals in usual care plus receive links to four webpages, one of which contains a video, that are stored within the patient portal's health information library. The educational material is currently distributed by Healthwise and includes information on the aetiology, symptoms and treatment of CRC as well as screening modalities and the interpretation of screening results.[36] With the exception of the one video, all material is static, and none is individually tailored.

Similar to participants in the experimental treatment group, participants enrolled in usual care plus are sent a follow-up module. The reminder module, which is also not tailored, is sent 2 weeks after the initial module. It includes a welcome screen and a link to the National Cancer Institute's CRC screening website.[52] This webpage provides patients with information on CRC screening and serves as a comparable alternative to the Healthwise information initially provided to the usual care plus. This allows the usual care plus group to run parallel to the experimental treatment in both timing as well as breadth of content provided (figure 3).

Usual care

Patients randomised to usual care receive CRC screening information and instructions as routinely provided by the health system. While the same Healthwise material that is being pushed to patients enrolled in usual care plus is available to these participants via the health library accessible within the EHR, unlike in usual care plus, participants are not being systematically directed to this material. Thus, while patients in this arm, by virtue of their portal account, have access to the same Healthwise material on CRC and CRC screening, access to the library containing these documents is not readily identifiable within the portal. Similarly, those materials could be printed for patients at the time of an office visit, but to our knowledge, this rarely, if ever, happens.

Analysis plan

The primary outcome for the evaluation is a binary variable (EHR-documented CRC screening use within 12 months as defined above), which will be available regardless of treatment assignment or consent status. Secondary outcomes, all measured at the time of the follow-up survey, are ordinal categorical (eg, screening intent and benefits) or continuous (eg, barriers and screening support) and available among consenters only, regardless of treatment assignment. Each outcome Y will be conditional on treatment assignment T and consent C (the interaction terms of), which will identify four groups: consenters (C=1) and non-consenters (C=0) assigned to treatment (T=1) and usual care plus or control (T=0).

For the effectiveness evaluation (H1), differences in CRC screening between experimental treatment and usual care plus will be estimated by a hierarchical logit model where patients who consented are nested within physicians. Because we will obtain CRC screening use data from the EHR with the absence of screening data coded as 'no screening', there will not be known missing values for the primary outcome. For a limited number

of trial participants (who, for whatever reason, elect to receive screening elsewhere), this may result in unknown missing values. While this will represent a trial limitation, we do not have reason to expect this missingness to differ by study arm.

For secondary outcomes (H2 and H3), we will use hierarchical generalised linear models and hierarchical linear models to analyse categorical and continuous outcomes, respectively, where patients who consented are nested within physicians.[53] We will compare the treatment effects for consenters, moderated by patient characteristics, to test H4 for aim 2. For H2–H4, we will handle missing data from survey item non-responses and unit non-responses efficiently by analysing all observed data.[54–56]

For the impact evaluation, we will compare screening rates across the three trial arms for consenters and non-consenters by a hierarchical logit model, analysing the entire sample. The effects of consenters will be compared with each other and those of non-consenters to describe the population represented by the experiment. We will also analyse a hierarchical model for the consent outcome C, which will describe who the beneficiaries of the treatment and usual care plus are in terms of their characteristics. One difficulty is that each patient in the usual care arm is missing the consent status. That is, if the patient was assigned to the other arms, he or she would have or would not have consented to study participation. We will view missing consent as missing data and estimate the hierarchical models by efficient handling of missing data, that is, by all observed data.[54–58]

Power and sample size calculations

To account for the clustering of patients nested within physicians, statistical power for the primary effectiveness evaluation (ie, the comparison of outcomes between the experimental treatment and usual care plus) was estimated using an R program written by Dr Jessaca Spybrook implementing the method in Spybrook and Hedberg, and Moerbeek *et al*.[59 60] With randomisation at the patient level, we consider a 95% plausible interval for CRC screening use in the experimental treatment (66%±5%) at alpha=0.05 in the usual care plus arm. With 1800 patients seen by 150 primary care physicians, or 12 patients per physician (6 in the experimental treatment and 6 in the usual care plus), we have 0.86 power to detect a 7% change in CRC screening rates between the experimental treatment and the usual care plus (ie, 66% vs 59%, respectively).

Trial status

As indicated in figure 2, prior to opening trial enrolment, 19 085 patients were identified as potentially eligible and randomised (7752 to the experimental treatment, 7626 to usual care plus and 3707 to usual care). The trial opened for enrolment at 13:00 eastern standard time on 14 June 2017 with recruitment planned to end in early 2019. Seven months into trial recruitment (14 January 2018), 2175 of the potentially eligible patients have received a primary care physician order for CRC screening (1110 in the experimental group and 1065 in the usual care plus group). This has resulted in n=328 patients being enrolled in the experimental group and n=376 in the usual care plus group. We have identified two barriers to trial enrolment among those receiving a physician order for CRC screening, and thus an invitation for trial participation. First, approximately 30% of patients who are sent an email notification that they have a new portal message never log into their portal account to read the message. In addition, among patients who log into their portal account and read the message, about 50% elect not to open the attachment that includes information on the trial (eg, consent information) and the decision support programmes. We are currently using in-depth interviews with patients who elected not to log into their portal account or not to open the attachment to gain insights into other means by which to engage such patients with decision support following physician recommendations for care.

Ethics and dissemination plan

The Institutional Review Board (IRB) approved the trial under an expedited review and, given the benefit/risk ratio, waived the need for written patient consent. A Health Insurance Portability and Accountability Act (HIPAA) waiver of authorisation was received to enable the inclusion of the usual care group. The trial is funded by the National Cancer Institute (7R01CA197205).

Findings, whether positive or negative, will enable clinicians and other healthcare stakeholders to make informed decisions about how to integrate new portal technology to support primary care patients in their decision making and service receipt. We will disseminate emerging stories, lessons learnt and findings on an ongoing basis. Manuscripts and presentations will be prepared for publication in diverse scientific venues, and we will target brief reports and presentations for the clinical, quality improvement and EHR communities as well as make use of emerging online repositories.

Data requests can be submitted to the corresponding author at the UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, after conclusion of the trial and publication of the primary manuscript.

DISCUSSION

To our knowledge, this is the first trial to test an online practice-integrated, postvisit CRC screening decision support programme that does not rely on direct human resources to help patients address lingering questions about CRC screening and overcome personal and structural barriers to screening use once a physician recommendation is in hand. As such, we are testing an intervention that fills an important gap in clinical care that has yet to be addressed. Our trial and programme are unique in their use of clinical workflow-integrated automation. By automating patient identification

and programme delivery, we are facilitating programme sustainability should e-assist: Colon Health succeed. By intervening with patients following a regularly scheduled office visit in which they received a physician recommendation for CRC screening, we are able to use a naturally occurring clinical event as the cue for patient action, thereby capitalising on the known powerful relationships between patients and their physicians. By using the patient portal to do so, we are ensuring that e-assist: Colon Health is fully integrated within existing clinic processes. The e-assist: Colon Health programme will extend, in a personalised and autonomy-supporting manner, the patient–physician CRC screening decision-making process beyond the confines of office visits. Thus, unlike traditional decision aids administered prior to a visit, we do not anticipate that e-assist: Colon Health will alter the patient–physician office visit interaction per se; instead we expect e-assist: Colon Health to extend the patient's ability to consider CRC screening in a supportive setting postreceipt of physician recommendation and to improve the patient's perception of the autonomy support they receive from their doctor's office. The fact that the programme is accessed via an existing patient portal furthers its integration with increasingly common clinic processes, streamlines patient accessibility and begins to address prior challenges of implementation faced by previous decision aid studies.

Recent reviews indicate that, compared with usual care, people who use decision aids benefit from improved knowledge, a better understanding of their values and enhanced participation in the decision-making process.[23 61 62] Despite the known benefits of decision aid use, physicians voice concerns regarding their practicality and,[22 63] to date, their integration within practice is limited.[21 22] Our trial, via our ongoing engagement with clinician and other healthcare stakeholders, is illustrating how these barriers can be overcome. The challenge is that while communication outreach strategies embedded within a patient portal may be sustainable and acceptable to healthcare stakeholders, they engage only a small subset of the patient population.[64] Furthermore, there is increasing evidence that use of a portal among those with an account varies, with patients from traditionally disadvantaged publications being relatively less engaged even once they have a portal account.[65 66] Our trial and its decision support intervention appears to be no exception. Thus, an overarching limitation of the trial is that its reach is limited to those already engaged with the portal. Prior studies have repeatedly shown this to be a relatively small segment of the population, and one in which minorities and other traditionally disadvantaged populations are under-represented.[67–76] In addition, our trial is limited by its implementation and recruitment within one health system that may further limit the ability to generalise results.

Facilitating the timely use of CRC screening among primary care patients requires that scalable programmes be designed to address barriers to obtaining a physician recommendation for care and the quality of that recommendation and the personal and system barriers faced once patients have a physician recommendation for care. Identifying sustainable strategies to support patient adherence to evidence-based care is critical for patient-centred medical homes and other delivery settings if we are to effectively and efficiently deliver preventive health services. Supporting patient adherence to known effective preventive health services is also critical to the ability to reduce the morbidity and mortality associated with preventable diseases such as CRC.

Author affiliations
[1]Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA
[2]Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA
[3]Henry Ford Health System, Detroit, Michigan, USA
[4]Department of Biostatistics, School of Medicine, Virginia Commonwealth University, Richmond, Virginia, USA
[5]Center for Community Health Integration, School of Medicine, Case Western Reserve University, Cleveland, Ohio, USA
[6]Case Comprehensive Cancer Center, Cleveland, Ohio, USA
[7]Department of Medicine, Center for Health Communications Research, Michigan and Ann Arbor VA Center for Clinical Management Research, Ann Arbor, Michigan, USA
[8]Department of Epidemiology and Biostatistics, College of Public Health, Temple University, Philadelphia, Pennsylvania, USA
[9]Fox Chase Cancer Center, Philadelphia, Pennsylvania, USA
[10]School of Public Health, University of Michigan, Ann Arbor, Michigan, USA
[11]School of Social Work, Michigan State University, East Lansing, Michigan, USA
[12]Department of Internal Medicine, University of California Davis Health, Sacramento, California, USA
[13]University of California Davis Comprehensive Cancer Center, Sacramento, California, USA

Acknowledgements We greatly appreciate the support we received from Mr Joshua Brown, Ms Patrice Fleming, Ms Ellen Nixon and Ms Nonna Akkerman, who provided help compiling study protocol material and descriptions. We also thank VCU biostatistician Ms Xiaoyan Deng for help with SAS coding the randomisation.

Contributors Conceptualisation: all authors. Drafting: JEL and YS. Reviewing: all authors.

Funding This work is supported by the National Cancer Institute grant numbers R01CA197205, R01CA166375, P30CA016086 and P30CA46592.

Competing interests None declared.

Patient consent Not required.

Ethics approval All aspects of the trial protocol have been approved by the Henry Ford Health System Institutional Review Board (protocol number 10060).

Provenance and peer review Not commissioned; externally peer reviewed.

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