Information With or Without Numbers For Optimizing Reasoning About Medical Decisions (INFORM)

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Research Plan

A. BACKGROUND:

IMPACT OF THE CONDITION ON THE HEALTH OF INDIVIDUALS AND POPULATIONS

Colorectal cancer (CRC) poses a significant burden in the US population, worsened by the low utilization of screening tests that have been proven to save lives. Each year in the United States, over 140,000 people are diagnosed with CRC and more than 50,000 die from it, making it the second leading cause of death from cancer in the US. [1] Much of the morbidity and mortality could be prevented with the appropriate use of available, approved, affordable screening tests. Just 59% of eligible adults are up to date with recommended screening, a rate that falls far short of screening for other cancers, such as mammography and pap tests.[2] Increasing uptake of CRC screening to 70% could save 35,000 lives over 5 years.[3]

One factor that can help improve screening is the availability of multiple approved tests, allowing individuals to choose a test that best fits their preferences. While there are some differences among the leading guidelines[4-6] – all recommend three tests: colonoscopy every 10 years, flexible sigmoidoscopy every 5 years, or annual stool testing with high-sensitivity fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT). Although one guideline prefers colonoscopy,[5] all three conclude that average-risk patients should be offered a choice among the recommended tests.

Colonoscopy is the most sensitive and specific for identifying polyps or cancers, but it carries significant burdens, risks, and expense. Colonoscopy is an invasive procedure involving a one- or two-day preparation to clean out the colon, IV sedation, and the need to take a day for the procedure and arrange a ride home. There are expenses, including possible charges for pathological analysis of any removed polyps. Finally, there are significant risks, including hemorrhage and perforation.[4]

Stool occult blood testing is the second most commonly utilized approach. Of the two recommended types, we concentrate here on FIT since it is widely used and available in the clinics where the study will be conducted. Stool blood testing has the advantage of being carried out by the patient in his or her home, is low cost, and requires no preparation. The main limitations are that it must be done annually, requires the patient to handle his or her own stool, and any positive test requires evaluation with colonoscopy. A major perceived drawback of stool testing, perhaps especially by primary care physicians rather than patients, is that it provides inadequate or inferior screening, since a stool test may fail to identify a polyp or cancer.

Despite its lower sensitivity, though, annual FIT with colonoscopy for any positive test produces a lifetime reduction in mortality from CRC that approaches, equals, or even exceeds that produced by colonoscopy,

according to several comparative effectiveness analyses.[7,8] The reasons for this include: (1) repeated application of FIT increases sensitivity, (2) only a percentage of polyps that are not identified will progress to cancer, (3) other sources of bleeding in the colon may lead to a positive FIT and thus trigger a colonoscopy where a non-bleeding polyp or cancer is identified; (4) colonoscopy is not a perfect test: polyps may be missed or may develop into cancers between screenings.

This point bears repeating: Although colonoscopy is the best test for identifying polyps or early cancers *on a single application*, it is not known if this translates into significantly superior reduction in morbidity and mortality for all patients. FOBT and FIT are approved in every major guideline because they are good screening tests. Patients who wish to avoid the burdens and risks of colonoscopy may reasonably choose stool blood testing, as acknowledged by all the published guidelines, and many patients do appear to prefer them.[9-15]

Studies also show that when primary care providers discuss CRC screening, they often fail to describe alternatives to colonoscopy.[16-18] This raises concern that failure to inform patients about alternatives to colonoscopy may lead patients to choices that do not truly match their preferences and may result in their failing to be screened. In a recent study, an outreach program that recommended just colonoscopy for screening resulted in a 38% uptake, while recommending a stool test or offering a choice between colonoscopy and stool test resulted in a 67% or 69% uptake, respectively.[19]

Multiple national organizations recommend that providers do a better job of describing and explaining the alternatives to colonoscopy: as one motto puts it, "The best test is the on that gets done."[20] An NIH consensus panel concluded that a major step in improving CRC screening is to ensure that all patients are informed about the full range of tests.[21] A nationwide initiative labeled "80% by 2018" (to achieve screening uptake of 80% by 2018) led by the National Colorectal Cancer Roundtable and joined by organizations such as the American Cancer Society, the American College of Gastroenterology, and others, embraces the goal of making all tests available.[20] A factor that motivates providers and healthcare systems to offer alternatives to colonoscopy is that quality measures count patients as screened if they undergo any approved test.

For all these reason, there is now strong pressure to make alternatives to colonoscopy available, and the main alternative to colonoscopy is stool testing, rather than sigmoidoscopy. A recent study found that under 1% of screened patients had sigmoidoscopy.[22] There are a variety of reasons: sigmoidoscopy is uncomfortable (no IV sedation or anesthetic), only examines half the colon, and has not been well reimbursed.[23,24] Other tests such as CT colonography are approved by some guidelines but not by others, and are not used widely. The DA that in this study will focus on the choice between colonoscopy and FIT.

2. Cross-cutting benefits: While this project focuses on CRC, determining how to best provide information about comparative effectiveness of screening strategies applies to other cancers as well, such as breast and

prostate. Although mammography is the standard screening test for breast cancer, for instance, patients may choose to be screened annually or biannually, with attendant benefits and risks.[25] Many experts assert that patients should be given information regarding the comparative effectiveness of such strategies.[26,27] This project can inform risk communication for screening for CRC and other cancers.

B. SIGNIFICANCE: POTENTIAL FOR THE STUDY TO IMPROVE HEALTH CARE AND OUTCOMES and **PATIENT CENTEREDNESS**

Opportunity to improve patient-centered care and outcomes: Informing patients about their options for CRC screening and their comparative effectiveness could produce higher quality decisions, improve the match between patient preferences and tests performed, and increase uptake of CRC screening. Decision aids (DAs) are a promising tool for accomplishing this goal. While DAs are not widely used in clinical medicine, a 2014 Cochrane review identified 115 randomized, controlled trials of DAs. These studies show that compared to usual care, DAs increase patient knowledge, improve patient-provider communication, and increase uptake of recommended interventions in many areas.[28] Ten randomized trials have tested a total of 7 different DAs designed for CRC screening.[29-35]

Information that is important to patients: Patients put a high value on comparative effectiveness information regarding CRC screening tests, especially the accuracy and sensitivity of tests,[12,36,37] and the risk reduction they provide,[38-40], and this information has a large impact on their decision-making.[13-15] This has been shown by multiple studies that compared patient interest and response to a wide range of relevant information.[12-15,36-38,40,41] We have also received comments from patients in multiple settings about the importance of information about accuracy and risk reduction provided by CRC screening tests. While patients have mixed feelings about receiving specific numbers (e.g. as percentages), many want some indication of the tests' comparative ability to protect them from cancer.

Critical gap in current knowledge: At the same time, little is known about how to optimally provide comparative effectiveness information to patients, especially whether such information should be given qualitatively (using words) or quantitatively (using numbers, graphs, and figures), and whether the best format varies based on patients' level of interest and ability. Studies showing that individuals value comparative effectiveness information did not directly compare the impact or acceptability of alternative ways of presenting such information. For instance, some studies described sensitivity using just words ("colonoscopy is better at finding polyps than other tests"),[9,10,12,42-44] while others presented numbers.[11,14,38,40]

Although guidelines for the design and evaluation of DAs recommend presenting comparative effectiveness information using detailed quantitative data, this recommendation is not evidence-based. The International Patient Decision Aids Standards (IPDAS), for instance, the most widely applied guidelines for the design and

implementation of DAs, recommend that DAs disclose quantitative data regarding absolute baseline risk (no screening), risk reduction provided by each test, and chance of false positives and negatives. IPDAS recommends presenting this information using frequencies and graphs, especially "icon charts" or "pictograms," using a variety of frames (e.g. gain vs. loss).[26,45,46] This recommendation appears to be based on the assumption that such data will help patients make fully informed decisions.

It is not known whether inclusion of such information improves decision-making or screening outcomes. In fact, research has shown that quantitative data may hinder individual decision-making for the following reasons:

- Low numeracy: At least 22% of adults have only the most basic quantitative skills, such as counting, while another 33% possess only slightly more advanced math skills, such as simple arithmetic.[47,48] Thus, more than half of adults cannot comprehend key mathematical concepts used in quantifying risk and benefit (probability, percentage, frequency). Even individuals with moderate numeracy have difficulty interpreting and applying information about risk and risk reduction provided by CRC screening tests.[49]
- Heuristics and biases: Psychologists, economists, and other researchers have identified numerous aspects of human thought process that lead to irrational responses to risk information.[50,51] To give just two examples: "Denominator neglect" leads people to exaggerate small dangers, such as a risk that occurs 5 times per 1,000,000, due to focusing on the numerator.[52] "Optimism bias," leads to underestimating the danger of a behavior (e.g. smoking) due to a belief that one will be in the group that is not harmed.[53]
- Gist: According to "dual-process" models of human reasoning such as Fuzzy Trace Theory, people form two representations of risk: the first represents the specific probability (in "verbatim memory"), while the second reflects a "gist impression" of its importance.[52-54] According to such models, the gist impression has more power than the verbal memory to influence opinions and actions.[54]

For all these reasons, inclusion of quantitative information in DAs may have no effect, or even negative effects on patient decision making. Worse, it may reduce screening uptake due to confusion or misunderstanding, a true "lose-lose" outcome. While such a decline in uptake would be acceptable if it was due to patient understanding and rational choice, it is a truly unfortunate outcome if it is the result of confusion.

The research necessary to identify the impact of quantitative information, and thus help guide the design of future DAs, has not been done, as noted in a number of reviews. A recent Cochrane review of all randomized, controlled trials of Das[55] found that just 25 studies examined DAs that presented probabilities.[56-73] These studies found that patients who viewed DAs with probabilities were more likely to correctly answer questions regarding these probabilities than individuals in the control group. But these studies found no clear benefit to presenting probabilities in terms of uptake or other outcomes. Further, in 24 of the 25 studies of DAs that included probabilities, no comparisons were made to DAs that were identical except lacking those probabilities. Many studies compared the DA containing quantitative information to a much simpler

information packet or website. The single randomized trial that varied the form of quantitative information used scripts read to participants (an extremely simple DA) and only included elderly patients.[35]

Variation in current practice: Among the 7 DAs for CRC screening tested, there is significant variation regarding the type of comparative effectiveness data provided. In addition, studies suggest that presenting this data in certain ways reduces uptake and did not improve patient understanding or decision-making. Four of the DAs provided no numbers,[29-32] and three provided information regarding the risk reduction or other numbers.[33-35] The three DAs that increased uptake provided no numbers regarding risk reduction, sensitivity, or specificity of the screening tests.[30,31,74] And the three DAs that provided at least some quantitative information found either no change in uptake,[33,35] or lower uptake, compared to controls.[34] An editorial published with one of these studies[34] suggested that the reduction in uptake could have been caused by patient misunderstanding of the quantitative information provided: "Although it is important to describe risks clearly, the amount of space given to the presentation of risk within DAs might be disproportionate to the conceptual facts adults consider when offered screening, and this may over-emphasize the risks associated with screening compared with the value of preventing the disease." [75, p. 949]

Preliminary Studies: Study Design and DAs: Our group conducted a randomized, controlled trial where 108 patients ages 50-75 years old who were at average risk for CRC and were due for CRC screening were randomized to use one of two DAs. The Control Group used a DA including just the *Basic Information* module, which provides general information about CRC, screening with colonoscopy, sigmoidoscopy, and FIT, including comparative effectiveness information presented verbally (no numbers).

The Quantitative group used a DA comprised of the Basic Information module followed by the *Quantitative* module, which included six slides with numbers and icon charts presenting the following values for average risk individuals:

(1) lifetime CRC incidence and CRC mortality (3%, or 30 per 1000), assuming no screening,
(2) lifetime CRC mortality given regular screening with colonoscopy (0.46%, or 4.6 per 1000) or with FIT (0.6%, or 6 per 1000), according to the SimCRC model,
(3) frequency of an individual FIT turning positive (50 per 1000) and of serious complications from colonoscopy (1-2 per 1000).

Finally, the Quantitative module presented a bar chart displaying average lifetime CRC mortality with no screening, colonoscopy, and FIT.

Participants answered a questionnaire before and after viewing the intervention (T0 and T1), regarding qualitative and quantitative knowledge, subjective risk of CRC, intent to be screened, and decision conflict. Participants were contacted after six months (T2) and asked about screening behavior and the electronic health record was checked for confirmation.

Results: Members of both Control (n=52) and Quantitative groups (n=56) showed significant increases from T0 to T1 in qualitative and quantitative knowledge ($p < .001$), perceived CRC risk (p-value = 0.005), intent to be screened (p-value < 0.001), intent to undergo FIT (p-value < 0.001), intent to undergo colonoscopy (p-value = 0.007), and reduction in overall decision conflict score (p-value < 0.001). However, no significant between-group differences in change scores on these variables were observed, with one exception: quantitative knowledge scores were higher in the quantitative group ($p < .01$).

When all variables were examined for interaction with numeracy, two were significant: perceived risk and intent to undergo FIT. Among participants at above-median numeracy, those in the quantitative arm had a significantly smaller increase in subjective risk for CRC than those in the control arm (-0.09 vs. 0.81, $p = .009$), and a significantly greater intent to undergo FIT (1.00 vs. 0.1, $p = .01$). There were no significant differences in these outcomes among participants whose numeracy scores were below the median.

At 6 months, a higher proportion of patients in the Quantitative arm had completed CRC screening compared to those in the Control arm; however, this difference was not significant (39.3% vs. 26.9%, $p = 0.173$). Differences between groups in the proportion being screened with FIT or colonoscopy also were not significant. Among patients with above-average numeracy, there was a higher uptake of FIT in the Quantitative group, compared to those in the Control group, that approached significance (12.1% vs. 0%, $p = 0.148$); no differences between groups were seen in the low numeracy group.

Conclusions:

(a) Adding quantitative information to a DA had limited impact overall and on patients with below-average numeracy from T0 to T1. But over six months there was a trend towards increased uptake overall among those shown quantitative information, compared to those shown only non-quantitative information.
(b) Among patients with above-average numeracy, providing quantitative information produced a significantly smaller increase in perceived CRC risk and a larger increase in intent to undergo FIT from T0 to T1. Also among patients with above-average numeracy, at six months there was a non-significant trend towards increased uptake of FIT by those who viewed quantitative information, compared to those who did not.

Applying Findings to Influence Design of DAs: The results of a larger trial could have significant impact on the design of DAs in the future. For instance, consider the following three results scenarios and the conclusions that could be drawn about the design of DAs in this area:

a. Finding that quantitative information significantly increases overall uptake for patients with all levels of numeracy would support *providing such data to all patients*.

b. Finding that quantitative information has a significant effect on perception and behavior only for patients with above-average numeracy would support *providing quantitative data only to those patients*, perhaps by making it optional.
c. Finding that the quantitative information does not improve knowledge in significant ways and reduces uptake for patients with all levels of numeracy, would suggest that DAs should not present quantitative information in this way, even as an option.

These are only three possible types of findings of the project. Of note, the approach supported by results of type (b) – allowing patients to *choose* whether to view quantitative comparative effectiveness information – would differ in important ways from current recommendations and design of DAs.

C. STUDY DESIGN AND APPROACH

1. RANDOMIZED, CONTROLLED TRIAL: SPECIFIC AIMS 1 AND 2:

Specific Aim #1: To compare screening intention, screening behavior, and perceptions of patients eligible for CRC screening who view a decision aid (DA) that includes quantitative information versus a DA without such data. We will also collect measures of decision quality.

Hypotheses:

1.1) Participants who view the DA with quantitative information will have larger increases in (a) perceived risk of CRC and (b) benefits of screening, compared to those who view the DA without such data.
1.2) A larger percentage of participants who view the DA with quantitative information will (a) intend to be screened and (b) complete screening at 6 months, compared to those who view the DA without such data.

Specific Aim #2: To determine whether numeracy moderates the effect of quantitative information.

Hypotheses:

2.1) Among participants with above-average numeracy, those who view the DA with quantitative information will have (a) smaller increases in perceived risk of screening and (b) larger increases in perceived benefit of FIT, compared to than those who view a DA without such data.
2.2) Among participant with above-average numeracy, a larger percentage of those who view the DA with quantitative information will (a) intend to be screened with FIT, and (b) undergo screening with FIT within 6 months, compared to those who view the DA without such data.

Study Design: To achieve these aims, we will conduct a randomized, controlled trial to compare outcomes between two groups: patients who view a DA that presents quantitative information regarding comparative effectiveness of colonoscopy and FIT (Quantitative group) and those who view the same DA without such quantitative information, which describes comparative effectiveness only verbally (Control group).

Choice of Study Design: This study compares two established approaches to describing comparative effectiveness of CRC screening tests. As described above, roughly half of the DAs regarding CRC screening that have been tested include quantitative information about risk, risk reduction, and other factors. No previous research has compared two DAs that are identical except that one presents comparative effectiveness information in quantitative terms.

Our trial compares the *efficacy* of these DAs since it only enrolls patients who match certain criteria and agree to be enrolled. We considered the option of enrolling all potentially eligible patients, but rejected this option due to the limited outcomes we could measure (i.e. just screening rate); such a study could not assess impact on understanding, perception, intention, and decision quality.

Choice of Comparators: As in the pilot study, those in the Control group will view a *basic information module*, based on the one used in our preliminary studies. Those in the Quantitative group will view the *basic information module* and a *quantitative module*, again based on the one used in pilot. We have already modified the *basic information* module based on input from patients who participated in our preliminary study and have now participated in three group discussions carried out after participation. In particular, we have increased clarity regarding the procedure and risks of colonoscopy and the fact that lack of a family history and lack of symptoms does not imply the absence of polyps or cancer.

We also plan the following changes in the *quantitative module*, in part to match the recommendations of IPDAS and in part based on input from patients who participated in group discussions and serve on the Patient Advisory Board. Using icon charts and numbers (proportions and frequencies), we will state average lifetime incidence with and without screening, and probability of false positives and false negatives after colonoscopy and FIT. In the first three months of the project, we will make these modifications and conduct cognitive interviewing with patients who view the DAs. We will also show the modules to the Patient Advisory Board and Community Advisory Board for input, discuss the cognitive interviewing, and make final changes.

Choice of Outcomes: Screening behavior, a primary outcome for this study, can be assessed reliably, and is central to assessment of a DA. Perceptions of risk of CRC and benefit of screening, and intention to undergo screening, is also relevant to evaluation of impact of a DA. We have chosen to assess Test Choice (see Measures, below) to measure concordance between intention and behavior, a measure that has been recommended to assess quality of decision-making.[76-79] We chose not to assess concordance between patient

characteristics and stated preference due to significant methodological and conceptual difficulties, following Sepucha (2010) and others.[76,80] We will also use the decision conflict scale, which has well validated psychometric properties and has been used in many studies of DAs to assess decision quality.[55,81] The decision conflict scale is limited, though, since it measures patients' feelings about their decision rather than the decision itself.[80]

Theoretical framework: Our theoretical framework is provided by the Health Belief Model,[82] which has been previously applied to research on CRC screening behavior.[83-85] We expect that, compared to patients who view the DA without quantitative information, those who view the DA with quantitative information will have a larger increase in perceived risk of CRC and the benefit of screening, resulting in a larger increase in intention to undergo screening (hypothesis 1.1), and higher screening rate (hypothesis 1.2). This fits with the Health Belief Model's assumption that action is caused by perception of susceptibility to the illness and benefit from the action.[82]

We also expect that among patients with above-average levels of numeracy, those who view the quantitative information will have a smaller increase in perceived risk of CRC, and will have a larger increase in perceived benefits of FIT, compared to those who view the DA without quantitative information (Hypothesis 2.1). According to the Health Belief Model, this larger perceived benefit should lead to a higher percentage choosing FIT as their intended screening behavior, and eventually in a higher percentage undergoing this test within six months (Hypothesis 2.2), compared to those who do not view the quantitative information.

METHODS:

Modification of DA modules, utilizing input of Patient Advisory Board: Prior to implementing the trial, we will modify the two DA modules that we have used in pilot testing, as described under Choice of Comparators, above, in keeping with the advice of our Patient Advisory Board. We will pilot test the new modules by conducting cognitive interviewing with 20 eligible patients who will not be enrolled in the study. We will present the modified DAs and the result of this cognitive interviewing to our Patient Advisory Board and Community Advisory Board within 2 months of the initiation of our project, to allow final changes and initiation of the study on time.

Conduct Trial: Study Design is shown in **Figure 1**. Sites: We will use three groups of primary practices: (1) Five IU Health practices previously belonging to the Methodist Medical Group (*MMG*); (2) Four IU Health practices previously belonging to the IU Medical Group (*IUMG*); and, (3) Two Eskenazi Health practices. These eleven primary care sites served over 22,000 individual patients in 2013-14, approximately 7500 of whom are eligible for CRC screening. These clinics serve a range of socioeconomic groups, ranging from upper-income suburban (Carmel, Fishers), to middle-income urban/ suburban (Greenwood #1/ #2, Glendale), to lower-income urban (E. Washington, W.38th St.)

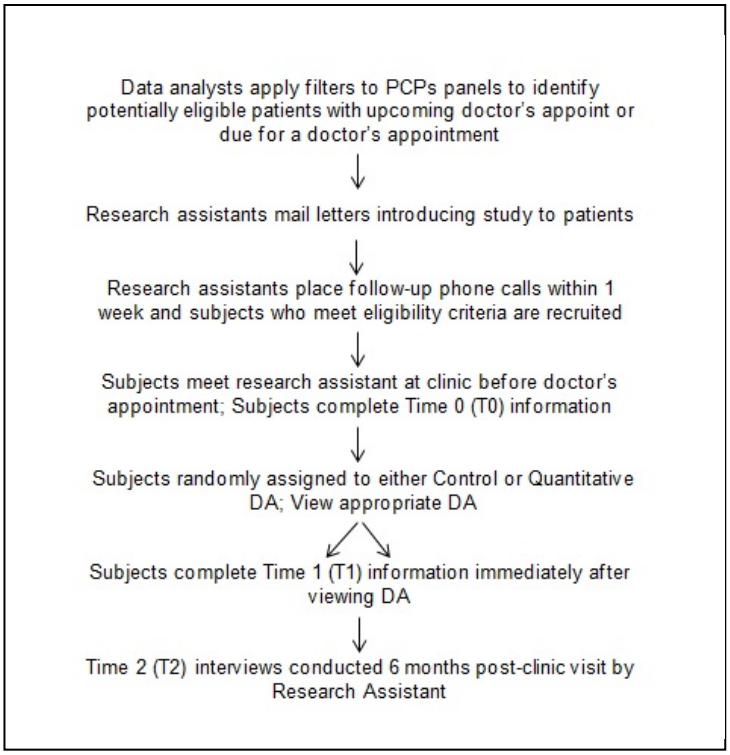
Inclusion and Exclusion Criteria: Patients will be *eligible* if they are (1) age 50-75 years and (2) have not had colonoscopy performed in last 10 years, sigmoidoscopy in last 5 years, or fecal occult blood testing (including FIT) in last 1 year. Patients will be *excluded from consideration* if they are (1) undergoing workup for symptoms consistent with colon cancer, such as weight loss or rectal bleeding, (2) have a diagnosis or medical history conferring elevated risk for CRC including polypectomy or colon cancer, inflammatory bowel disease, certain inherited syndromes, or a significant family history of CRC, or (3) are unable to speak and read English.

Recruitment: As shown in Table 1, we believe that approximately 7500 patients seen in the 11 clinics in 2013-14 were eligible for CRC screening (based on electronic health information used to report quality measures). Given this pool of potentially eligible patients, we are confident we can recruit 15 patients per week, which would allow us to achieve our goal of 720 patients in 48 weeks. Of note, our timeline allows 68 weeks (16 months) to complete recruitment. We have an established track record of successful recruiting in the IU Health system, in the preliminary studies reported above and other pilot research. In these studies, recruiting just from the five MMG clinics, we recruited 8-10 patients per week when our systems were optimized. The inclusion of the IUMG IU Health clinics and Eskenazi clinics more than doubles potentially eligible patients. The ResNet system, which will assist with recruitment at the IUMG and Eskenazi clinics, has a 40-year history of successful recruitment efforts.

Patients Ages 50-75 years old

		Screening Status	
	Total # Seen****	Due	Up to Date***
IU Health MMG Clinics*			
East Washington	4470	1207	3263
Greenwood #1	2151	698	1453
Greenwood #2	2650	661	1989
Fishers	1693	353	1340
Carmel	1915	389	1526
IU Health IUMG Clinics*			
Eagle Highlands	946	195	751
Epler Parke	1366	743	623
Glendale	1936	853	1083
Avon	1372	535	837
Eskenazi Clinics**			
On-campus clinic/ W38th	4454	1868	2586
TOTAL	22953	**7502**	15451

* Seen April 1, 2013 - March 31, 2014
** Seen Jan 1, 2013 - Dec. 31, 2013
*** Colonoscopy within 10 years, sigmoidoscopy within 5 years, or FOBT/ FIT within 1 year
**** Excluding those with total colectomy or history of CRC



Randomization: Our biostatistician will generate a stratified randomization scheme (i.e., within each clinic) that will be implemented by the research assistants.

Subject recruitment and enrollment: Potentially eligible patients will be identified using a query of the electronic medical record system, either by the IU

Health Clinical Research Systems working in partnership with the Regenstrief Data Core (for IU Health sites), or solely by the Regenstrief Data Core (for Eskenazi sites). IU Health patients with an upcoming doctor's visit or Eskenazi patients who are due to be seen will be sent a letter of introduction and explanation about the study signed by the patient's physician. The letter will also include a phone number that patients can call to "opt out" of being contacted. A week later, the research assistant will call patients who have not called the "opt out" number to explain the study and answer questions about study requirements, potential risks, and compensation. The research assistant will make an appointment for eligible, willing patients to meet the research assistant at the clinic before a clinic visit. For those patients who refuse to be assessed for eligibility, or who are eligible but refuse to participate, the RA will record reasons they are willing to share. In addition, we will collect demographic, insurance, and other information about those who refuse to participate, as allowed by the IRB.

Intervention Delivery: As in the preliminary studies, the DA will consist of a Powerpoint presentation with audio track that the patient views and controls on a laptop. At the clinic meeting, the RA will review inclusion and exclusion criteria and obtain written informed consent and for patients who are willing, HIPAA waiver to allow an EMR check for screening uptake. Patients will then complete the baseline questionnaire (Time 0 (T0)), be randomized to Control or Quantitative arm, and use the appropriate DA.

Data collection and follow-up: Data collection for assigned patients will occur at three time points: 1) Baseline (T0), before using the DA; 2) immediately after viewing the DA (T1), and; 3) Six months after randomization (T2). T2 data will be elicited by telephone call by a research assistant who is blinded to the patient's trial group assignment. Data will be entered directly into a REDCap survey (by the patient at T0 and T1; the research assistant at T2) that flags any missing data, which has minimized missing data in our preliminary studies. At the time of T2, the EMR will be accessed to confirm screening uptake, again by a research assistant blinded to the patient's group assignment. Subjects will receive compensation in the form of gift cards after the clinic meeting ($30) and T2 phone call ($20).

Outcome measures and time of collection:

- Perceived risk for CRC (T0 and T1): Five-item scale containing items originally developed by Champion to measure perceived breast cancer risk[86,87] and a measure of perceived age and gender-adjusted comparative risk,[88] recently applied to CRC screening.[89] Each item uses a four-point response option, where 1 = very unlikely and 4 = very likely, to assess participants' beliefs about how likely they are to get CRC in the next 5 years, in the next 10 years and sometime during their lifetime. Two items assess likelihood of getting CRC if they do or do not have regular colon testing.[89]
- Perceived benefit of screening (T0 and T1): Assessed separately for colonoscopy and FIT, using items drawn from validated scales for measuring benefits, barriers, and self-efficacy of colonoscopy and FIT.[89-91] All scales have Likert responses (1 = strongly agree to 5 = strongly disagree).

- Screening intention (T0 and T1): *Which of the following do you think you will do in the next 6 months?* (Choices: Get a colonoscopy, Get a stool test, Get another colon test, Not get any colon test, Don't know)
- Decision conflict (T0 and T1): The Decision Conflict Scale is a sixteen-item instrument that assesses patients' subjective feeling regarding the decision process over five areas. Each item is a likert-style question with five-point response option, where 1= strongly agree and 5 = strongly disagree. This scale has well documented psychometric characteristics and has been used in many studies of DAs.[81]
- Screening behavior: Six-months after viewing the intervention, participants will be asked whether they have completed colonoscopy, FIT, other screening, or no screening, and results will be checked with the electronic medical record. Discrepancies between patient report and the EMR will be investigated and evaluated according to procedures established in our pilot studies. Screening rate will be calculated.

Additional measures: We will also collect the following information regarding participant characteristics to examine covariation and explore moderation effects:

- Knowledge of CRC and CRC screening (T0 and T1): *Qualitative knowledge* assessed with eight True/ False questions regarding general information (including risk factors, screening test options, and test frequency) and *quantitative knowledge* (T1) assessed with four multiple-choice questions regarding probability of outcomes, as in the pilot study.
- Numeracy (T0) will be assessed with the Subjective Numeracy Scale, a validated instrument that involves 8 Likert-style questions.[92,93]
- Literacy (T0) will be assessed with the REALM-SF instrument.[96]
- Demographic data (T0) (including age, gender, income, education), as well as data on personal and family medical history, previous screening, and previous MD recommendations, utilizing a questionnaire that has been used by our team and other researchers in multiple studies of CRC screening.[89]

Analytic methods: Sample Size Justification: For the two quantitative aims, our primary outcome is CRC screening behavior (recoded as yes or no). For Aim 1, in our pilot study we found a difference in overall CRC screening rates between the control and quantitative group to be 14/52=26.9% vs 22/56=39.3%, a difference we consider to be clinically important. In order to detect this difference with a two-sided chi-square test and level of significance of 0.05, a sample size of 241 per group (482 total) is needed.

For Aim 2, when examining the interaction of numeracy and the intervention, our preliminary data suggests there will be no intervention effect on FIT in the low numeracy group, but that in the high numeracy group the intervention will lead to an increase in FIT of about 12% (0% in control group vs. 12.1% in quantitative group). Using the data from our pilot, the sample size needed was determined based on the calculations provided in Demidenko (2008)[95] for detecting an interaction between two binary covariates (intervention group and numeracy) in a logistic regression model. We assumed the probability of being in either intervention group or in either numeracy group of 0.5, prevalence of FIT of 0.2, and odds ratio for FIT based on intervention group

=1.68, odds ratio for FIT based on numeracy = 0.45, and odds ratio of numeracy by intervention group = 1. In this case we would need a total of 600 (300 per group) to have 80% power (alpha=0.05) to detect an interaction OR of 3.2, which is similar to the interaction OR estimated from our preliminary data of 3.7. Thus, to have sufficient power for both aims, we will target a total of 600 evaluable patients.

This sample size will provide ample power for our other outcomes, which are all ordinal or numerical scales. For example, in examining the interaction of perceived risk and numeracy in Aim 2, we would have 99% power to detect the hypothesized interaction based on the means and standard deviation of this outcome from our pilot study. In our pilot study the attrition rate was 17.2% (39 of 227 recruited patients). We will allow for a dropout rate of 20%, and thus we will enroll 720 total participants. In addition to allowing for attrition, we will plan to enroll possibly 30 more participants. This is because we want to continue with our recruitment procedures until we reach our recruitment goal. This may mean that potential participants will be sent a recruitment letter during the same week that we reach our goal. We want to be able to follow-through with our recruitment procedures with these people even if we have met our recruitment goal. We aim to enroll 11-15 patients per week, to achieve our goal, in 45-66 weeks. Our timeline allows 68 weeks (16 months) to complete recruitment.

Data Management and Analysis Plan: We will create a secure web-based system to capture study data using the REDCap database management system. We will review and process data using multiple verification and edit checking programs (e.g. range-checks, missing data reports). We will also conduct rudimentary analyses to ensure that the data have been properly collected and to identify any outliers or errors. A consort diagram will be constructed for reporting that accounts for all missing data.

For Aim 1, our primary analyses will be to compare intention and overall CRC screening rates and the perceived risk and benefits of CRC screening between the two groups using either mixed effects logistic regression (for CRC intention and screening) or linear mixed models (for perceived risk and benefits) that include a random effect for clinic. Similar analyses will be used to compare FIT and Colonoscopy intention and screening rates and perceived risk and benefits. In addition we will do supplemental analyses treating CRC intention and screening as a three-level outcomes (yes/don't know/no) and fit multinomial logistic regression models to explore if there are differences between those that respond don't know vs no (relative to yes). For Aim 2, our primary analysis will be to compare the outcomes by group and numeracy (split into low and high based on the median) using the same general modeling strategy described above. Main effects for intervention and numeracy will be included in the model as well as an intervention-by-numeracy interaction term and random effect for clinic. If the interaction term is significant, we will test the intervention effects separately in the two numeracy groups.

Other analyses to be conducted and reported will include basic descriptions of all study variables by group and time, assessment of internal reliability for scales by Cronbach's alpha, assessing changes of time by group in for potential mediators by ANCOVA, exploring mediation effects using MPLUS software, exploring moderation for a few key variables (knowledge, literacy, demographics), and examining decision quality. To examine mediation, the effect sizes for the direct, indirect, and total effects will be estimated and tested for the paths from intervention group membership to the intervention mediators (perceived risk and benefits) and from mediators to primary outcomes (screening). Moderation will be assessed using the same methods described for numeracy in Aim 2. To assess decision quality, we will calculate concordance between intention and behavior for FIT, Colonoscopy, Don't Know, and No screening using kappa statistics for each group and compare the kappa values using a chi-square test.[96] We will assess the direction of the discordance by examining the two-way contingency tables that cross-classify intention and actual screening outcome. We will compare decision conflict over time between the two groups using linear mixed models. Finally, we will tabulate refusal reasons and reasons why screening is not up-to-date at enrollment and compare refusers to enrollees using two sample t-test, chi-square tests or Fisher's Exact test as appropriate.

Sensitivity analysis will be conducted for each outcome to assess the effects of the covariance structure on the results and determine which covariance structure is appropriate. Other assumptions, such as normality of residuals, will also be checked and appropriate modifications to the analysis plan applied if needed, such as transformations or use of non-parameteric methods. All analyses will be intent-to-treat. From our pilot study, we expect missing data to be minimal (less than 2%) for subjects during participation. Thus, for missing data on scales we will use mean imputation as long as two-thirds of the questions have been answered (or per validated instrument instructions, if otherwise). Longitudinally, we expect attrition to be less than 20%. We will compare T0 information for those lost to follow-up to those that are not to investigate the plausibility of the data being missing at random (MAR), and conduct pattern mixture models analyses to see how the results could change based on the MAR assumption.

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