Increasing CRC Screening Using Audio and Video Brochures:
A Pilot Randomized Controlled Trial

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disposable gloves, a dish sample collection device, and a mailed reminder. Both developed FIT outreach interventions will be compared to usual care (FIT, manufacturer's instructions).

Currently, FIT outreach programs are used in the United States. It is important to mail the FIT kits to patients without prior consent to reduce the selection bias that would occur if consent was obtained prior to the mailing. Patients will be mailed a notification letter one week prior to mailing the FIT kits and may contact the health center to opt out of future mailings.

2. SPECIFIC AIM

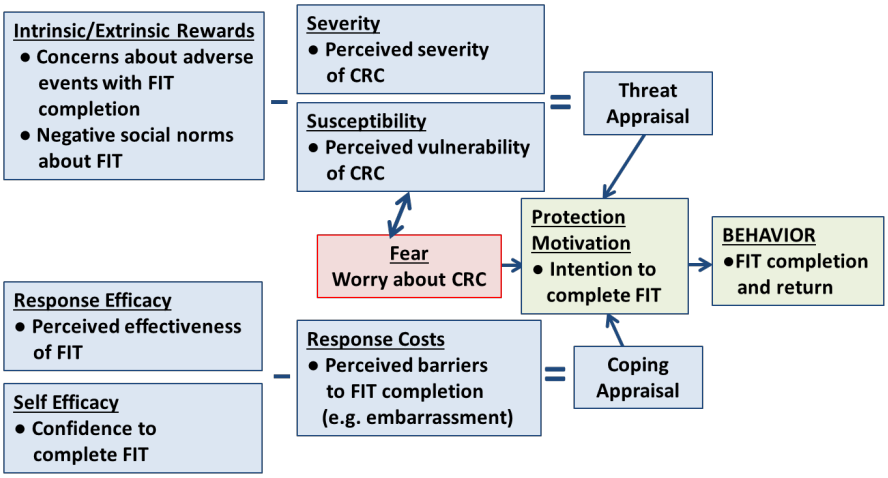
The specific aim for this study is to: **Conduct a pilot study of the two developed mail-based FIT outreach interventions vs. mailed usual care materials to establish acceptability and obtain preliminary efficacy data on increasing CRC screening.** Hypothesis A. FIT return and CRC screening process (primary outcome) will be higher among mid-life adults in both intervention groups (audio or video brochures) compared to those in the usual care group (*preliminary efficacy*). Hypothesis B. Mid-life adults in both intervention groups will have higher satisfaction with materials compared to those in the usual care group (*intervention acceptability*).

3. METHODS
Pilot Study: Randomized Controlled Trial

Conceptual Model.

The intervention will be guided by the Protection Motivation Theory (PMT; Figure 2).[22] Constructs include: intrinsic/extrinsic rewards of the maladaptive response (concerns about adverse events, negative social norms); severity/susceptibility (perceived CRC severity and vulnerability); response efficacy (FIT effectiveness); self-efficacy (confidence to complete FIT); and response costs (screening barriers). Fear is a mediating variable between severity and vulnerability and intention and focuses on CRC worry.

Figure 2. Protection Motivation Theory for FIT



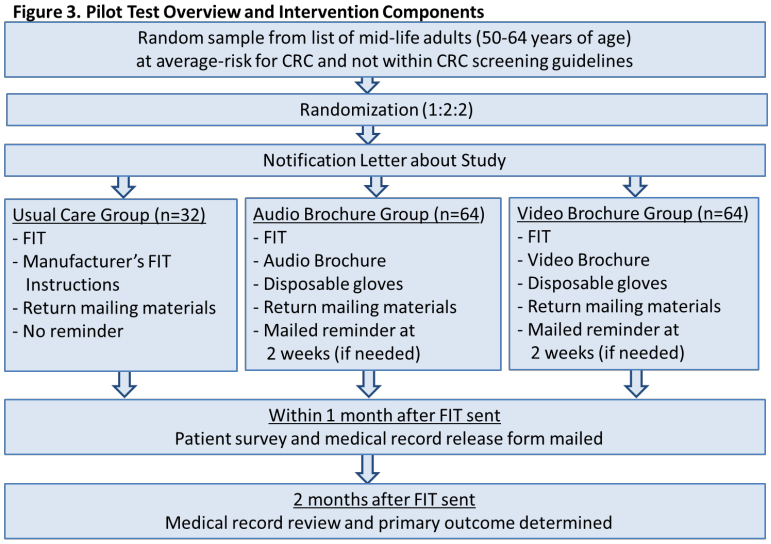
Eligibility/ Recruitment.

A list of patients will be generated at the participating health system (COMPASS Community Health Center; letter of support Appendix A) of mid-life men and women (50-64 years old) who: 1) live in Appalachia; 2) had a medical visit in the past two years; 3) are at average-risk for CRC (no history of CRC, polyps, inflammatory bowel disease, family history of CRC or hereditary CRC syndromes); and 4) are not within CRC screening guidelines (no fecal occult blood test/FIT in the past year; flexible sigmoidoscopy in past five years; colonoscopy in past ten years).[4] Only one person per household will be able to participate in the study to avoid any bias. The Compass Community Health Center will share patient names and addresses with Dr. Katz at OSU using secure email for all communication.

Randomization.

The selected patients will be randomized to the: 1) usual care group; 2) audio brochure group; or 3) video brochure group. A random number generator will be used and a 1:2:2 allocation scheme (stratified by gender). We will continue until 160 patients have been randomized (Figure 3).

Figure 3. Pilot Test Overview and Intervention Components



Intervention Groups.

The intervention groups will be sent (Table 1) a **Notification letter** (Appendix B) about the CRC screening study. If an individual opts out of participation in the study, there information will not be retained and their information will be deleted from the file by Dr. Katz when she is notified by the health center.

Approximately 7 days later, patients will be sent a kit that includes an **Information Sheet** (Appendix C) explaining the content of the kit and instructions on what to do depending on the group assignment.

FIT. The test and postage-paid return addressed envelope is included with the manufacturer's FIT instructions (Appendix D). An audio brochure or video brochure (described next) will be included in the kit. Participants only have to place their name, date of birth, and the date of their sample collection on the requisition form and the specimen collection bottle. They will be able to put the completed FIT in the mail using the return stamped addressed envelope.

Audio Brochure or Video Brochure. The audio brochure cover (Appendix E) and audio script (Appendix F) or video brochure cover (Appendix G) and video script (Appendix H) will provide targeted CRC screening information (6 minutes and 45 seconds) and will include FIT instructions (5 minutes and 30 seconds) in a format that will be engaging for individuals with limited health literacy. We enhanced the cultural appropriateness of the intervention by featuring pictures of individuals who look like adults from the Appalachian community and healthcare providers focusing on the CRC burden among Appalachian residents since targeted health information improves health outcomes.[23-25] Due to COVID-19, we were not able to film the videos in Appalachia. We are using narrative over high quality photographs that were reviewed and chosen by community input (community members and healthcare providers). The intervention content targets PMT constructs (described in Conceptual Model section). We included testimonials for likeness between source and receiver; improving cultural similarity and message relevance.

Disposable Gloves. To address the screening barrier about the concern with the messiness associated with FIT completion, we will include disposable gloves that can be worn during specimen collection.

Collection Device. To assist with the collection of the stool sample, we are also including a dish collection device that makes it easier to collect a stool sample.

Patient survey (Appendix I: audio brochure group; Appendix J: video brochure group) **and Medical Record Release (MRR) form** (Appendix K) will be included in the kit with the FIT test. The survey assesses demographic characteristics (e.g. race, education, etc. and telephone number), PMT constructs (e.g. screening barriers)[26], health literacy[27], perception of access to quality medical care, and satisfaction with educational materials using modified items from an existing satisfaction scale (Likert-type items).[28]. Patients will be asked to complete the survey even if they do not complete and return the FIT. Return of the survey will imply consent and participants will receive a $25 gift card for

completing the survey and a $5 gift card for the return of the signed MRR (Appendix L). Gift cards will be mailed to participants within three business days after receipt of the signed documents. Participants will not have to answer any survey questions they do not want to answer. Participants will be allowed to return the FIT without the survey or MRR. We will call patients who return the survey to decrease missing data, if needed. Based on our previous research, we expect 85% will return the survey and 70% will return a MRR. We will include a stamped addressed return envelope so individuals may return the documents.

Mailed Reminder (if necessary). A mailed reminder (Appendix M) will be sent to participants who have not completed the FIT about two weeks after the initial FIT test mailing based on community input. Previous research has shown that FITs are usually returned within a few months.[16, 19] Participants may request a 2nd FIT if they misplaced the first FIT. The study's primary outcome is based on if an individual returns or does not complete the FIT test at two months.

Table 1. Components of Usual Care Group and Intervention Groups

Component	Group(s)	Description	Theoretical Constructs
Notification Letter	All	• Recommendation for CRC screening	N/A
Patient Survey	All	• Demographic information • CRC screening history • FIT barriers/facilitators • Satisfaction with materials	• Severity, susceptibility • Rewards, response costs • Self-efficacy, Response-efficacy • Fear/worry
Medical Record Release	All	• Release of CRC screening results	N/A
FIT	Usual Care	• Manufacturing company FIT instructions	N/A
FIT	Audio	• Provides information about CRC screening • Brochure with targeted CRC information for residents of Appalachia, and testimonials • Provides step by step FIT audio instructions	• Severity, susceptibility, response efficacy • Rewards: Concerns and social norms • Fear/worry • Self-efficacy, response efficacy, response costs
FIT	Video	• Provides information about CRC screening • Brochure with targeted CRC information for residents of Appalachia, and testimonials • Provides step by step FIT visual and audio instructions	• Severity, susceptibility, response efficacy • Rewards: Concerns and social norms • Fear/worry • Self-efficacy, response efficacy, response costs
Disposable Gloves	Audio/Video	• Addresses a common patient barrier ("messiness")	• Response Costs
Dish Stool Collection Device	Audio/Video	• Addresses a common patient barrier (ease of collection)	• Response Costs
Screening reminders (if needed)	Audio/Video	• Mailed reminder about the importance of completing CRC screening (FIT)	• Rewards, response costs • Self-efficacy, Response-efficacy

Usual Care Group.

The usual care group will be sent a **Notification letter.** This letter will be Identical to intervention groups (Appendix B).

One week later patients will be sent a kit (Table 1) that includes an **Information Sheet** (Appendix C) explaining the content of the kit and instructions on what to do based on the group assignment.

FIT. The test and postage-paid addressed return envelope is included with the manufacturer's FIT instructions (Appendix D). Participants only have to place their name, date of birth, and the date of their sample collection on the requisition form and specimen collection bottle. They will be able to put the completed FIT in the mail using the return stamped addressed envelope. The FIT test will be sent

directly to the laboratory that works with the community health center. The FIT test will not be sent to OSU.

Patient survey (Appendix N) **and Medical Record Release (MRR) form** (Appendix K)**.** The survey assesses demographic characteristics (e.g. race, education, etc. and telephone number), PMT constructs (e.g. screening barriers)[26], health literacy[27], perception of access to quality medical care, and satisfaction with educational materials using modified items from an existing satisfaction scale (Likert-type items).[28] Patients will be asked to complete the survey even if they do not complete and return the FIT. Return of the survey will imply consent and participants will receive a $25 gift card for completing the survey and a $5 gift card for the return of a signed MRR (Appendix L). Gift cards will be mailed to participants within three business days after receipt of the signed documents. Participants will be allowed to return the FIT without the survey or MRR. We will call patients who return the survey to decrease missing data, if needed. Based on our previous research, we expect 85% will return the survey and 70% will return a MRR. We will include a stamped addressed return envelope with the documents. Identical to intervention groups, participants may request a 2nd FIT if they misplaced the first FIT. The study's primary outcome is based on if an individual returns or does not complete the FIT test.

Surveys. The surveys will be designed using Teleform software by the Recruitment, Intervention and Survey Shared Resource (RISSR). This paper-based data collection software reduces error associated with data entry and directly inputs data into a database that is saved behind the OSU firewall.

Study Primary Outcome: FIT Return.

FIT return at 2 months will be the primary outcome of this pilot study.

FIT Results and Follow-Up.

The laboratory will send FIT results to the health center and participants will be notified of results per the health center's regular protocol. Participants with normal FITs will be mailed results including an explanation of the results and the importance of annual FIT completion. Participants with positive FITs will be called by the healthcare system to discuss results and will be referred for colonoscopy using current referral process. Participants with a positive FIT that cannot be reached by multiple attempts by telephone will be sent a letter instructing them to call the clinic for the FIT results. For participants who provide MRR, we will document FIT results. We will also document subsequent referral for colonoscopy, other CRC tests (e.g. colonoscopy) completed, and test results. Dr. Hussan will assist with issues associated with follow-up of positive FIT that may arise during the study, if needed (all participants). If we do not have a signed MRR, the healthcare system will send us group data by study arm.

Data Analysis.

The specific aim of this proposal is to conduct a pilot study of the two developed mail-based FIT outreach interventions vs. mailed usual care materials to establish acceptability and obtain preliminary efficacy data on increasing CRC screening. Large sample sizes will not be required to achieve these goals. **Hypothesis A.** Mid-life adults in both intervention groups will have higher satisfaction with materials compared to those in the usual care group (*intervention acceptability*). Linear regression will be used to compare means and estimate differences (intent-to-treat analysis). These acceptability data will be critical to our subsequent application. **Hypothesis B.** FIT return (primary outcome) will be higher among mid-life adults in both intervention groups (audio or video brochures) compared to those in the usual care group (*preliminary efficacy*). We will randomize 64 patients in each intervention arm and 32 patients in the control arm (160 total, stratified for gender in each arm). This sample size will also allow us to characterize proportions +/-6% and means +/-0.13 standard deviation units in each intervention arm. We will estimate FIT return (primary outcome) using proportions for each study group. We assume

a return rate of 20% in control arm, 40% in audio brochure arm (OR=2.7), and 50% in video brochure arm (OR=4.0) based on the literature. Both comparisons (each intervention compared to control) will be a two-sample test of proportions (intent-to-treat analysis) using a one-sided alpha of 0.1 due to the preliminary nature of the study. With these assumptions, we have 96% power for the test of the video intervention and 77% power for the test of the audio intervention. We know that we will not be powered to detect small effect sizes or conduct sophisticated analyses (e.g. gender differences). We will estimate critical parameters with point estimates and 95% confidence intervals and provide a preliminary test of effectiveness on FIT completion. Results will provide preliminary data that will help power the future larger RCT. Data between the healthcare system and the OSU research team will be by secure encrypted email (Appendix O)

Survey Non-Responders.

Due to the low return of completed surveys, an additional follow-up will be conducted. A letter from the health center participating in this study will be sent to patients who have not returned a completed survey and: a) who have not completed the FIT test (Appendix AA), or b) who have completed the FIT test. If a patient calls the toll-free number and is willing to complete the telephone interview, a script (Appendix CC) will be read prior to starting the interview that will include obtaining verbal consent for the telephone interview.

After verbal consent has been received, the interview will start. A few introductory questions and the interview guides (Appendix DD) are the approved surveys with a few less questions to decrease burden. The six different interview guides are based on what arm of the study (usual care, audio brochure, video brochure) the person was sent and whether they completed or did not complete the FIT test. Participants will be mailed the $25 gift card if they complete the telephone interview. This additional opportunity to collect information from patients is important for revising the intervention prior to testing in a future trial.

4. Privacy of Participants.

Precautions will be taken to protect the privacy of the participants. Identification numbers will be used instead of the names of participants on study forms and in the database containing survey data. The OSU study team will keep a separate file with study ID numbers and patient names (Appendix P). Only Dr. Katz at OSU will have access to the file with the names and addresses and participant ID numbers and this information will be password protected behind the OSU Medical Center firewall. The names, addresses, and participant ID numbers will also be known by the health center so that all further communication between Dr. Katz and the health center will be by using participant ID numbers. Patient surveys and signed medical record release forms will be stored in locked file cabinets behind locked doors in Dr. Katz's office. All study-related databases will be password protected behind the OSU firewall and any other documents will be stored in locked file cabinets behind locked doors. In addition, all study-related activities will take place in the home of the participants, which helps to protect their privacy.

We believe this study presents only minimal risk to participants, which is far outweighed by the potential benefit to both the participants and society in general. Colorectal cancer screening by a recommended screening test is an important health-related issue for adults living in Appalachia, and this study will provide knowledge about a new method to increase screening among this high-risk population.

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