

Receipt, uptake, and satisfaction with tailored DVD and patient navigation interventions to promote cancer screening among rural women

Susan M. Rawl^{1,*}, Ryan Baltic², Patrick O. Monahan³, Timothy E. Stump⁴,
Madison Hyer⁵, Alysha C. Ennis⁶, Jean Walunis⁷, Katherine Renick⁸, Karen Hinshaw⁹,
Electra D. Paskett¹⁰, Victoria L. Champion¹¹ and Mira L. Katz¹²

¹Simon Comprehensive Cancer Center, School of Nursing, Indiana University, Indianapolis, IN, USA,

²Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA,

³Department of Biostatistics and Health Data Science, School of Medicine, Indiana University, Simon Comprehensive Cancer Center, Indianapolis, IN, USA,

⁴Department of Biostatistics and Health Data Science, School of Medicine, Indiana University, Indianapolis, IN, USA,

⁵Center for Biostatistics, College of Medicine, The Ohio State University, Columbus, OH, USA,

⁶College of Public Health, The Ohio State University, Columbus, OH, USA,

⁷Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA,

⁸The Ohio State University, Columbus, OH, USA,

⁹Indiana University School of Medicine, Indianapolis, IN, USA,

¹⁰College of Medicine, Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA,

¹¹School of Nursing, Indiana University, Simon Comprehensive Cancer Center, Indianapolis, IN, USA,

¹²College of Public Health, Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA

*Correspondence address. Indiana University School of Nursing, 600 Barnhill Drive, NU 345E, Indianapolis, IN 46202, USA. Tel: 317-698-1943; E-mail: srawl@iu.edu

Abstract

Process evaluation is essential to understanding and interpreting the results of randomized trials testing the effects of behavioral interventions. A process evaluation was conducted as part of a comparative effectiveness trial testing a mailed, tailored interactive digital video disc (DVD) with and without telephone-based patient navigation (PN) to promote breast, cervical and colorectal cancer screening among rural women who were not up-to-date (UTD) for at least one screening test. Data on receipt, uptake, and satisfaction with the interventions were collected via telephone interviews from 542 participants who received the tailored interactive DVD ($n = 266$) or the DVD plus telephone-based PN ($n = 276$). All participants reported receiving the DVD and 93.0% viewed it. The most viewed sections of the DVD were about colorectal, followed by breast, then cervical cancer screening. Most participants agreed the DVD was easy to understand, helpful, provided trustworthy information, and gave information needed to make a decision about screening. Most women in the DVD+PN group, 98.2% ($n = 268$), reported talking with the navigator. The most frequently discussed cancer screenings were colorectal (86.8%) and breast (71.3%); 57.5% discussed cervical cancer screening. The average combined length of PN encounters was 22.2 minutes with 21.7 additional minutes spent on coordinating activities. Barriers were similar across screening tests with the common ones related to the provider/health care system, lack of knowledge, forgetfulness/too much bother, and personal issues. This evaluation provided information about the implementation and delivery of behavioral interventions as well as challenges encountered that may impact trial results.

Lay summary

Two interventions to promote cervical, breast, and colorectal cancer screening among rural women who were not up-to-date (UTD) for at least one screening test were evaluated by rural women who received them as part of the randomized trial. Participants who received the tailored interactive digital video disc (DVD; $n = 266$) or the DVD plus telephone-based patient navigation (PN; $n = 276$) were interviewed by phone about their engagement and satisfaction with the interventions. All participants reported receiving the DVD and 93.0% viewed it. Most agreed the DVD was easy to understand, helpful, provided trustworthy information, and gave information needed to get screened. Almost all women in the DVD+PN group, 98.2% ($n = 268$) talked with the navigator. The most common cancer screenings discussed with navigators were colorectal (86.8%), followed by breast (71.3%) and cervical (57.5%). The average length of encounters with the navigators was 22.2 minutes; navigators spent 21.7 additional minutes on coordinating activities. Barriers discussed were similar across screening tests. The most common were related to the healthcare provider/system, lack of knowledge, forgetfulness/too much bother, and personal issues. This study provided important information about receipt, uptake, and satisfaction with two behavioral interventions, along with challenges encountered that may impact results.

Keywords: cancer screening; rural women; tailored intervention; patient navigation; process evaluation

Graphical Abstract

RISE Study Process Evaluation

POWER THROUGH PREVENTION

RISE: RURAL INTERVENTIONS FOR SCREENING EFFECTIVENESS



DVD watched
(n=503)



Strongly Agreed/Agreed that DVD

- Was easy to understand and helpful
- Gave information that was important, and I could trust
- Included scenes I could relate to, women like me, and people I could trust
- Should be sent to other women in my community



Patient Navigation
(n=268)



Strongly Agreed/Agreed that Patient Navigator

- Was easy to understand and helpful
- Gave information that was important, and I could trust
- Was convenient and covered the right amount of information
- Average time of encounter = 22.2 minutes
- Should talk to other women in my community about cancer screening

Implications

Practice: Interventions that can be successfully delivered to rural women in their homes to increase completion of needed cancer screening tests should be integrated into clinical practice settings.

Policy: Policymakers and health systems who want to increase participation in early detection and prevention of cancer through screening should support cost-effective, accessible, and acceptable interventions that can be widely implemented to reach rural populations.

Research: Future research should include comprehensive process evaluation to assess the receipt, uptake, and satisfaction of effective interventions to increase cancer screening participation.

Introduction

Residents in rural areas of the United States (U.S.) experience higher cancer incidence and mortality rates, as well as lower screening rates compared to those in metropolitan areas [1–5]. Cancer disparities among rural populations have been linked to social determinants of health including socioeconomic status (SES), lifestyle factors, access to health care, health insurance, or a combination of these factors [3–6]. Many rural women do not complete cancer screening at recommended intervals [5]. In an observational study conducted among rural women in Appalachian Ohio, medical record-validated completion of guideline-based screening were low: 32% for breast cancer (BC), 36% for cervical cancer (CC), and 30% for colorectal cancer (CRC) [7]. Only 8.6% of the women were up-to-date (UTD) for all three cancer screenings [7].

Prior studies showed sociodemographic factors limit UTD screening for these cancers among rural populations. Such

factors include lower educational attainment, less knowledge about screening, lower income, poor access to health care, and greater social deprivation [1]. Given the substantial contribution guideline-based cancer screening provides for lowering cancer mortality [2–4] effective interventions to increase breast, cervical, and colorectal cancer screening could increase rates of being UTD with screening guidelines and decrease the disparate cancer mortality experienced by rural women [5].

These data suggest that cost-effective interventions are needed to support adherence to cancer screening guidelines for rural women. To address this need, we conducted a comparative effectiveness trial to test the hypothesis that the addition of telephone-based Patient Navigation to a tailored interactive Digital Video Disc (DVD+PN) will be more effective than either a mailed DVD alone or usual care (UC) [6]. The main efficacy results of this trial are reported elsewhere [8].

In addition to examining the outcomes of a health behavior change intervention, careful evaluation of the processes of delivering such interventions is essential. Understanding the degree to which interventions are delivered, received, taken up, and satisfactory to participants is necessary to interpret the success or failure of interventions as well as any limitations [9, 10]. Few studies have documented results of the process evaluation of screening interventions tested in randomized trials. While there are no standard methods for process evaluation of behavioral interventions, the approach used in this study was modeled after previous evaluations of similar interventions conducted by this team [11, 12].

Process measures are quantifiable metrics that provide information to describe the implementation process, including intermediate steps that lead to intervention outcomes. Process evaluation is used to identify how an intervention is delivered as well as implementation failures and/or problems that reduce the likelihood of achieving the desired outcomes [9, 13]. This paper reports the results of process evaluations of the two interventions, DVD and the DVD+PN, designed to promote BC, CC, and CRC screening among rural women who were not UTD with one or more screenings. The larger trial, including the process evaluation, was approved by the Institutional Review Boards at two midwestern universities.

Methods

Interventions to promote cancer screening

Detailed descriptions of the interventions have been published [6] and are briefly described here.

Tailored DVD intervention

The theory-based tailored, interactive DVD included an introduction and three separate sections focused on BC, CC, and CRC screening. The introduction focused on how cancer develops and the importance of being UTD for cancer screening. Each cancer site section started with a discussion of the importance of the specific cancer screening, an overview of screening test recommendations, and used narratives of women who addressed screening barriers and highlighted the importance of completing screening. Women received tailored messages based on their responses to questions they answered using the DVD remote control about their cancer screening history, risk factors, cancer knowledge, intention to get screened, confidence to complete cancer screening, and barriers to complete screening. Examples of barriers addressed in the DVD included: concerns about costs, pain, embarrassment, lack of transportation, finding a location to complete screening, and lack of doctor recommendation.

Patient navigation intervention

Patient navigators were experienced social workers who were trained by study investigators. Navigators had a comprehensive understanding of cancer screening tests, common barriers associated with those tests, and local rural culture and communities. They developed and maintained county-level resource lists that included healthcare facilities and screening services provided at each, health departments, and services such as transportation and childcare to better assist participants in their communities. Navigators had strong communication skills and used plain language when talking to community members. Navigators attempted to contact

women by phone, mail, or email approximately 1 week after the DVD was mailed and made up to ten attempts to reach each participant to complete navigation. Navigators tracked the number of contact attempts, information/content discussed during encounters, actions taken by the navigator to address screening barriers, and coordinating time spent on navigation activities in a computer-based navigator documentation system.

Navigators first contacted participants by telephone to ascertain whether they received and viewed the DVD. If a participant had not yet viewed the DVD, they were encouraged to do so, and a follow-up call was scheduled to begin navigation. Navigators assessed each woman's knowledge of needed screenings and then assessed barriers to getting screened. They provided additional educational information, mailed cancer screening brochures to participants who requested additional materials, addressed screening barriers, provided support and encouragement, and assisted with follow-up after any abnormal screening test. At exit, navigators also contacted any participant found to have been diagnosed with BC, CC, or CRC cancer during the intervention period to assist them if needed, regardless of a participant's randomization condition. To assess intervention fidelity, all navigator calls were recorded, and a random sample of recordings were reviewed by the project manager to confirm concordance between recordings of barriers, navigation provided, and data recorded by the navigators.

Recruitment, eligibility and randomization

Detailed information on recruitment methods and eligibility criteria are described in detail elsewhere [6]. Briefly, mailing lists of female residents aged 50–74 living in 98 rural counties in Indiana and Ohio were obtained from Marketing Systems Group (white pages, commercial and U.S. postal service lists). Promotional materials (flyers/brochures/postcards) were displayed in public spaces including libraries, senior centers, and health departments. Finally, targeted Facebook advertising was employed, focusing on age-eligible women who lived in target counties of both states. Eligible women were: (i) aged 50–74 years; (ii) not UTD (overdue) for one or more recommended screenings for BC, CC, or CRC; (iii) had no personal history of cancer (other than non-melanoma skin cancer); (iv) resided in one of the target counties in Indiana or Ohio; (v) able to speak/read English; (vi) able to provide informed consent; and (vii) able to access a device to play a DVD. The U.S. Preventive Services Task Force 2016 guidelines that were published at the time of the start of the study were used to determine whether a woman was adherent to screening guidelines [2–4].

Potentially eligible women were mailed a letter and information sheet introducing the study, followed by a telephone call by trained interviewers. In addition, potentially eligible women were able to contact the study team via a toll-free number or through the study's email address. Women who clicked targeted Facebook ads were directed to a REDCap page that included a description of the study, eligibility criteria, and a brief set of questions to partially assess eligibility and determine the best time(s) for an interviewer to contact the individual to complete the consent process and baseline survey.

During this initial phone call, interviewers explained the study, verified eligibility, obtained verbal informed consent

and conducted the baseline telephone survey. Of 1852 eligible participants who verbally consented to complete the baseline survey, 209 refused to provide consent to medical record review (MRR) to verify screening status for each of the three cancers. Participants were then mailed an additional short survey and a medical record release form with a stamped, pre-addressed envelope. Those who did not return the release form within 2 weeks were re-contacted by the interviewer. Documentation of screening tests in the medical record were verified by each woman's health care provider. Among the remaining 1643 women, 658 were found to be ineligible after MRR, leaving 985 eligible women randomized to one of three study arms: (i) 382 to the tailored interactive DVD alone (DVD); (ii) 388 to DVD+PN, and (iii) 194 to UC. Randomization was stratified by age (50–64 vs. 65–74 years old) and by seven categories reflecting each woman's needed cancer screening(s): (BC only, CC only, CRC only, BC+CC, BC+CBC, CC+CBC, or BC+CC+CBC).

Only women who were randomized to the two intervention study arms—those who received the DVD alone ($n = 382$) or the DVD+PN ($n = 388$) were asked to complete the process interview.

Data collection and measures for process evaluation

Data were collected through structured telephone interviews to evaluate receipt, uptake, and satisfaction with the DVD and DVD+PN interventions. Process evaluation interview calls commenced 2 months after mailing the DVD intervention. Ten attempts were made to reach participants by phone interviewers. Interview questions focused on the DVD receipt, viewing, and if participants had discussions with others about the DVD content. Four closed-ended items asked whether women had received the DVD (yes/no), viewed it (yes/no), which sections were watched (introduction, breast, cervical, and/or colorectal), and whether they discussed the DVD with others (yes/no). Women who did not watch the DVD were asked an open-ended question about why they did not watch it, and women who responded that they discussed the DVD with others were asked to indicate with whom they discussed it (spouse/partner, child, other family member, friend/neighbor, doctor/healthcare provider, or others).

Participants who viewed the DVD were then asked about their perceptions of the relevance, helpfulness, and satisfaction with the DVD's content. Women were asked to indicate their level of agreement with 12 statements on a 5-point Likert scale where 1 = strongly disagree to 5 = strongly agree. Statements included that the DVD: was easy to understand, was helpful, gave information that was new, gave information that was important, was embarrassing, took too long, was convenient, gave information that could be trusted, included women like me, included scenes I could relate to, included people I could trust, and should be sent to other women in my community.

To assess receipt of the PN intervention, women randomized to the DVD+PN group were asked if they received a call from the navigator (yes/no), had talked to the navigator (yes/no) or had intention to speak with the navigator (yes/no). If no contact occurred, reasons for not talking with the navigator were documented. If participants reported talking with the navigator, data were collected about the content of their discussion (BC, CC, and/or CRC screening) and whether they discussed screening with anyone after the navigator call (yes/

no). Those who reported a discussion with others were asked to indicate whom they discussed screening with (spouse/partner, child, other family member, friend/neighbor, doctor/healthcare provider, or others).

For participants who talked with the navigator, satisfaction, relevance, and helpfulness of the navigator was then assessed. Women were asked to indicate their level of agreement with 11 statements on a 5-point Likert scale where 1 = strongly disagree to 5 = strongly agree. Statements included that the navigator: was easy to understand, was helpful, gave information that was new, gave information that was important, discussed things that were embarrassing, covered just the right amount of information, took too much time, was convenient, was someone I could trust, sounded like she knew people in my community, and should talk to other women in my community about screening. Women were also asked to indicate their level of agreement on the same 5-point Likert scale with two additional statements: (i) the navigator gave me the information I needed to get: BC, CC, and/or CRC screening; and (ii) the navigator helped me decide to get BC, CC, and/or CRC screening.

Data on the number and types of contacts made by the patient navigator as well as the types of actions taken by navigators, including barriers addressed, were extracted from the computer-based navigator documentation database created for this study.

Analysis

Descriptive statistics are reported for the process evaluation. Specifically, categorical, and continuous variables were described with frequencies (%) and means (standard deviation), respectively. We also compared the demographic characteristics of women who completed the process interview ($n = 542$) with those who did not complete the process interview ($n = 228$) using Pearson's chi-squared test and two-sided Wilcoxon rank sum test for categorical and continuous demographic variables, respectively. The item response metrics of variables are described in the section above. Perceptions of the relevance, helpfulness, and satisfaction (12 items pertaining to DVD content and 11 items about the PN) were analyzed at the item level (i.e. as categorical variables) to report a rich and nuanced descriptive assessment, and because the percentage who agreed or strongly agreed provided an intuitive descriptive metric. Which variables were analyzed categorically or continuously is clearly discerned in all tables where we report frequency and percentage or mean (SD) and median (IQR) and range, respectively.

Results

Participant characteristics

Of 770 participants assigned to receive the interventions, 542 (70.4%) were reached to complete the process interview and provided data for this analysis. No significant differences were observed in the baseline characteristics of women who completed the process interview compared with those who did not (Table 1); no differences between completers and non-completers were observed when tested separately within intervention arm (not shown). Participants who completed the process interviews had a mean age of 58.8 years, 97.8% were White, 79.3% were married or living as married, and 86.8% had at least some college. Two-thirds were currently employed, 77.2% had annual household incomes above \$40

Table 1 Baseline characteristics by process evaluation completion status

Characteristic	Overall <i>n</i> = 770 ¹	Completed process interview <i>n</i> = 542	Did not complete process interview <i>n</i> = 228	<i>P</i> -value ²
Age at consent				.053
Mean (SD)	58.5 (6.3)	58.8 (6.5)	57.7 (5.8)	
Median (IQR)	58.0 (53.0, 63.0)	58.0 (53.0, 64.0)	57.0 (53.0, 62.0)	
Range	50.0, 74.0	50.0, 74.0	50.0, 74.0	
Race				.484
Non-White	19 (2.5)	12 (2.2)	7 (3.1)	
White	751 (97.5)	530 (97.8)	221 (96.9)	
Marital status				.061
Married/living as married	592 (77.0)	429 (79.3)	163 (71.5)	
Divorced/widowed/separated	146 (19.0)	93 (17.2)	53 (23.2)	
Never married	31 (4.0)	19 (3.5)	12 (5.3)	
Unknown	1	1	0	
Education				.129
HS/GED or less	114 (14.8)	71 (13.1)	43 (18.9)	
Some college or associate degree	297 (38.6)	210 (38.7)	87 (38.2)	
Bachelor's degree	192 (24.9)	135 (24.9)	57 (25.0)	
Graduate degree	167 (21.7)	126 (23.2)	41 (18.0)	
Currently employed				.538
No	255 (33.1)	181 (33.4)	74 (32.5)	
Yes—part time	134 (17.4)	89 (16.4)	45 (19.7)	
Yes—full time	381 (49.5)	272 (50.2)	109 (47.8)	
Household Income				.825
<\$40 000	144 (18.7)	103 (19.0)	41 (18.0)	
\$40 000–\$79 999	281 (36.5)	196 (36.2)	85 (37.3)	
\$80 000+	318 (41.3)	222 (41.0)	96 (42.1)	
Unknown	27 (3.5)	21 (3.9)	6 (2.6)	
Health insurance status				.132
None	37 (4.8)	23 (4.3)	14 (6.1)	
Public only	74 (9.6)	50 (9.2)	24 (10.5)	
Private only	529 (68.8)	367 (67.8)	162 (71.1)	
Public and private	129 (16.8)	101 (18.7)	28 (12.3)	
Unknown	1	1	0	
Smoking status				.162
Never	505 (65.6)	348 (64.2)	157 (68.9)	
Former	198 (25.7)	151 (27.9)	47 (20.6)	
Current	46 (6.0)	29 (5.4)	17 (7.5)	
Unknown	21 (2.7)	14 (2.6)	7 (3.1)	

Table includes participants randomized to the DVD and DVD+PN groups at baseline.

HS/GED, High School/General Educational Development.

¹ “Mean (SD = standard deviation),” “Median (IQR = interquartile range).”

² Pearson's Chi-squared test; Wilcoxon rank sum test.

000 with 41.0% reporting annual incomes above \$80 000, and 95.7% had health insurance.

DVD intervention

Descriptive statistics for the DVD intervention included receipt, adherence with viewing, and occurrence of discussions after DVD viewing (Table 2). All participants reported receiving the DVD, and 93.0% viewed it. Among the 39 women who did not view the DVD, 38 provided reasons (i.e. barriers) for not viewing it which included not having time (28.9%), failure to get around to it (21.1%), a malfunctioning DVD player (44.7%), or the DVD being difficult to use (7.9%). A high percentage of

participants watched DVD sections for each of the three cancer types (63%–77%). The sections with the highest viewing were CRC (76.9%) and BC (75.9%). Almost half (45.9%) of participants reported discussing the DVD with someone else after viewing it, with the most frequent discussion being with the participant's health care provider (37.7%).

Relevance, helpfulness and satisfaction with the DVD

Results for participants' perceptions of the relevance, helpfulness of, and satisfaction with the DVD are shown in Table 3. Overall, the percentage of participants who rated “strongly

Table 2 DVD receipt, adherence with viewing, and discussions ($n = 542$)

	<i>n</i>	%
DVD receipt and viewing		
Received DVD: Yes	542	100
Viewed DVD: Yes	503	93.0
Barriers to viewing DVD ($n = 38$) ^a		
No time	11	28.9
Did not get around to it	8	21.1
No DVD player/not working	17	44.7
DVD difficult to use	3	7.9
Other	3	7.9
DVD sections watched: ^a		
Introduction only	46	9.1
Breast	382	75.9
Cervical	317	63.0
Colorectal	387	76.9
DVD discussions		
Discussed DVD with others: Yes	231	45.9
Discussed DVD with: ^a		
Spouse/partner	44	19.0
Child	18	7.8
Other family member	45	19.5
Friend/neighbour	64	27.7
Doctor/Health care provider	87	37.7
Other (co-workers, patients)	18	7.8

DVD, Digital Video Disc.

^a Percentages exceed 100% because multiple responses were allowed. For example, 38 women reported 42 barriers to viewing the DVD.

agree or agree” was high for satisfaction, relevance, and helpfulness. Items that more than 90% of participants strongly agreed or agreed with included the DVD: “was easy to understand” (99.4%), “included people I could trust” (93.6%), “included scenes I could relate to” (92.0%), “gave important information” (97.8%), “gave trusted information” (96.6%), “was helpful” (95.0%), “was convenient” (91.8%), and “should be sent to other women in my community” (90.6%). Most women strongly agreed or agreed that the DVD gave them information they needed to get BC (86.6%), CC (87.0%), and CRC screening (91.0%). About half of women agreed that the DVD gave them information that helped them decide to get BC (49.9%) or CC screening (47.3%) while a larger percentage reported it helped them decide to get CRC screening (62.5%). Very few women reported that the DVD was embarrassing (1.4%) or took too long to watch (5.4%).

Patient navigation intervention

For the PN intervention, descriptive statistics for the receipt and for whether participants had screening discussions with the navigator during the call and/or with others after the call are shown in Table 4. Almost all women recalled receiving a call from the navigator (98.9%, $n = 273$), and 98.2% ($n = 268$) reported talking with the navigator. Among five women who did not speak with the navigator, reasons given were having no time and not getting around to watching the DVD ($n = 2$ each). The screenings that the largest percentage of women discussed with the navigator were CRC (86.8%) and BC (71.3%); only 57.5% of participants discussed CC screening with the navigator. About half of participants discussed

screening with someone after talking with the navigator, and the most frequent discussion was with the participant’s health care provider (45.6%).

Relevance, helpfulness, and satisfaction with the patient navigator

Data on participants’ perceptions of relevance, helpfulness, and satisfaction with the PN intervention are shown in Table 5. Items that 90% or more of participants strongly agreed or agreed included that the navigator: “was easy to understand” (99.6%), “was helpful” (98.5%), “gave information that was important” (97.4%), “covered just the right amount of information” (96.2%), “was convenient” (95.1%), and “was someone I could trust” (94.0%). A few women strongly agreed or agreed that the navigator “discussed things that were embarrassing” (6.0%) or that the navigator “took too much time” (4.1%). Only 20.1% thought “the navigator sounded like she knew people in my community,” although 89.4% strongly agreed or agreed that “the navigator should talk to other women in my community.” More than three-quarters of women strongly agreed or agreed that the navigator gave them the information they needed to get BC (77.0%), CC (77.6%), and CRC screening (83.9%). More than half of participants strongly agreed or agreed that the navigator helped them decide to get screened for BC (54.8%) and CC (51.0%) while almost two-thirds (64.8%) agreed that the navigator helped them decide to get screened for CRC.

Time spent and actions taken by patient navigators

Data on the amount of time spent with, and on behalf of, participants as well as the types of actions taken by navigators are listed in Table 6. Of the 276 participants assigned to receive navigation, 95.3% had at least one encounter (phone conversation) with a navigator. Participants had an average of four encounters with navigators with a range of 1–14. The total length of encounters as documented by navigators was 22.2 minutes on average with a range of 1–136 minutes. Navigators also documented the amount of time they spent on “coordinating” activities which included the amount of time they spent preparing for and following-up on the encounter. Such coordinating activities included finding resources for the participant, contacting clinics/providers, mailing additional materials, or making appointments. Navigators spent an average of 21.7 minutes, with a range of 1–102 minutes on coordinating activities for each participant. The total number of contacts made by navigators to reach participants was 22.8 (range = 2–73), with most being telephone contacts (mean = 15.2, range = 1–48). In addition, navigators’ actions included sending participants additional educational materials by U.S. mail an average of 5.3 times (range = 1–17), by email an average of five times (range 1–35), and by text only one time.

Barriers addressed by patient navigators

Navigators devoted a significant amount of time during their encounters discussing reported barriers to screening and offering support to overcome them. Figure 1 illustrates the barriers addressed by navigators in descending order of frequency. The most frequently discussed barriers were related to screening not being a priority because the participant had no symptoms/problems and concerns about the health care provider or health system (no screening recommendation, no provider, lack of trust, poor communication or discrimination, lack of knowledge and/or time).

Table 3 DVD: satisfaction, relevance and helpfulness (*n* = 503 patients who viewed DVD)

	Strongly agree/agree	Neutral/not sure	Strongly disagree/disagree
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Participants' perception of DVD			
Easy to understand	500 (99.4)	3 (0.6)	–
Helpful	478 (95.0)	13 (2.6)	12 (2.4)
Gave information that was new to me	275 (54.7)	56 (11.1)	172 (34.2)
Gave information that was important	492 (97.8)	6 (1.2)	5 (1.0)
Embarrassing	7 (1.4)	3 (0.6)	493 (98.0)
Took too long to watch	27 (5.4)	15 (3.0)	461 (91.7)
Gave information I could trust	485 (96.6)	12 (2.4)	5 (1.0)
Convenient	462 (91.8)	12 (2.4)	29 (5.8)
Included women like me	441 (88.9)	45 (9.1)	10 (2.0)
Included scenes I could relate to	460 (92.0)	34 (6.8)	6 (1.2)
Included people I could trust	467 (93.6)	30 (6.0)	2 (0.4)
Should be sent to other women in my community	453 (90.6)	36 (7.2)	11 (2.2)
Gave information I needed to get			
Breast cancer screening (<i>n</i> = 382)	331 (86.6)	21 (5.5)	30 (7.9)
Cervical cancer screening (<i>n</i> = 315)	274 (87.0)	18 (5.7)	23 (7.3)
Colorectal cancer screening (<i>n</i> = 387)	352 (91.0)	14 (3.6)	21 (5.4)
Gave information that helped me decide to get			
Breast cancer screening (<i>n</i> = 381)	190 (49.9)	42 (11.0)	149 (39.1)
Cervical cancer screening (<i>n</i> = 317)	150 (47.3)	35 (11.0)	132 (41.6)
Colorectal cancer screening (<i>n</i> = 387)	242 (62.5)	30 (7.8)	115 (29.7)

DVD, Digital Video Disc.

Table 4 Patient navigation (PN): receipt and discussions (*n* = 276 patients in DVD+PN group who completed the process evaluation interview)

	<i>n</i>	%
PN receipt		
Received call: Yes	273	98.9
Talked with navigator: Yes	268	98.2
Reason for not talking with navigator (<i>n</i> = 5)		
No time	2	40.0
Didn't get around to it (hadn't watched the DVD)	2	40.0
Other (rescheduled call, but no connection)	1	20.0
PN screening discussions		
Breast cancer screening	189	71.3
Cervical cancer screening	153	57.5
Colorectal cancer screening	230	86.8
Discussed screening with anyone after talking with navigator: Yes	136	51.3
Discussed with: ^a		
Spouse/partner	30	22.1
Child	6	4.4
Other family member	28	20.6
Friend/neighbour	31	22.8
Doctor/health care provider	62	45.6
Other (co-workers, insurance co., patients)	8	5.9

^a Counts exceed 100% because multiple responses allowed.

Most barriers were similar across screening tests but slight differences were noted (Table 7). While the top five barriers that were most frequently discussed were fairly consistent

across screenings (not a priority/no symptoms, provider/health care system barriers, lack of knowledge, too much bother/forgetfulness, and other health problems/disability), the number of navigator encounters where barriers to CRC screening were discussed was higher than other screening tests. Of the 3171 total barriers to screening discussed with navigators, 1904 (60.0%) were related to CRC screening with 1009 (31.8%) barriers to stool testing and 895 (28.2%) barriers to colonoscopy. Lack of knowledge and screening not being a priority was the most frequently cited barrier for stool blood testing.

Discussion

This paper reports the results of process evaluations for two interventions, DVD compared to DVD+PN, designed to promote BC, CC, and CRC screening among rural women who were not UTD with one or more screenings. In this study, all participants who completed the process interview reported receiving the DVD in the mail and 93% viewed it. Participants overwhelmingly agreed that the DVD was easy to understand, helpful, provided trustworthy information, and gave them information needed to make a decision about screening. Development of the DVD intervention required substantial investment of time and resources, but once developed, dissemination and delivery of the DVD through the U.S. mail were relatively easy and inexpensive.

Receipt, uptake, and satisfaction with the mailed DVD used in this study was very high and superior to several studies testing similar interventions [12, 14–16]. In another study conducted by this team, results of a process evaluation of a mailed interactive DVD designed to promote CRC screening among low-income and minority patients in a safety net hospital who

Table 5 Satisfaction, relevance and helpfulness of patient navigator ($n = 268$ patients in DVD+PN group who talked with navigator)

	Strongly agree/agree	Neutral/not sure	Strongly disagree/disagree
	n (%)	n (%)	n (%)
The Navigator...			
Was easy to understand	266 (99.6)	–	1 (0.4)
Was helpful	262 (98.5)	2 (0.8)	2 (0.8)
Gave me information that was new	154 (57.7)	34 (12.7)	79 (29.6)
Gave me information that was important	259 (97.4)	2 (0.8)	5 (1.9)
Discussed things that were embarrassing	16 (6.0)	5 (1.9)	246 (92.1)
Covered just the right amount of information	256 (96.2)	4 (1.5)	6 (2.3)
Took too much time	11 (4.1)	3 (1.1)	252 (94.7)
Was convenient	254 (95.1)	8 (3.0)	5 (1.9)
Sounded like she knew people in my community	52 (20.1)	116 (44.8)	91 (35.1)
Was someone I could trust	251 (94.0)	13 (4.9)	3 (1.1)
Should talk to other women in my community about screening	235 (89.4)	23 (8.7)	5 (1.9)
Gave me the information I needed to get			
Breast cancer screening ($n = 187$)	144 (77.0)	10 (5.3)	33 (17.6)
Cervical cancer screening ($n = 152$)	118 (77.6)	8 (5.3)	26 (17.1)
Colorectal cancer screening ($n = 230$)	193 (83.9)	9 (3.9)	28 (12.2)
Helped me decide to get			
Breast cancer screening ($n = 188$)	103 (54.8)	25 (13.3)	60 (31.9)
Cervical cancer screening ($n = 151$)	77 (51.0)	23 (15.2)	51 (33.8)
Colorectal cancer screening ($n = 230$)	149 (64.8)	24 (10.4)	57 (24.8)

did not attend their screening colonoscopy appointment were similar [12]. Katz *et al.* reported that of 243 participants randomized to receive the interactive DVD, 194 (80%) viewed it, 99% reported the DVD was helpful and 99% would recommend it to others. In the current study of rural women, a higher percentage (93%) of participants viewed the mailed DVD. Since this DVD included information on BC, CC, and CRC screening, the content may have been more salient to this study population.

In another study testing the effects of a complex intervention delivered to patients who had an expired order for colonoscopy, the intervention consisted of a personalized reminder letter from their physician, an educational brochure and a mailed DVD about CRC and screening [14]. Of 109 patients contacted for the process evaluation, 95% reported receiving the mailed materials, 98% reported reading the letter and brochure, but only 30% watched the DVD. Reasons for not watching the DVD were that participants: were too busy/had no time (32%); already had sufficient information about screening (21%); were not interested in screening (13%); or did not have or were unable to operate a DVD player (10%).

Levy and colleagues [15] conducted a process evaluation of a multilevel intervention to increase CRC screening. The intervention consisted of a mailed DVD plus written materials from the American Cancer Society and the Centers for Disease Control. They found that 67% of participants reported they viewed at least 75% of the DVD, 94% reported they understood at least 75% of the material, and 96% reported that the amount of material was just right. Zapka and colleagues [16] tested the effects of a mailed video to promote CRC screening to patients prior to a healthcare provider visit. Among 450 patients who received the mailed video, 193 (43%) viewed at least 50% of the video and 174 (39%) watched all of it. Of 243 patients who watched less than 50% of the video, 43%

watched none of it. Screening outcomes were directly tied to viewing the video.

In our study, higher viewership of the DVD may be due to a variety of reasons. Paramount to the success of these interventions was our use of community-engaged strategies in the planning, development, implementation, and evaluation of the interventions. We placed considerable value on feedback from community members and the input and recommendations from the study's community advisory board members. Additionally, this was a gender-specific study and females tend to be more focused on their health and willing to participate in, and follow through, with health-related interventions. Furthermore, the interactive nature of the DVD may have resulted in higher levels of engagement and viewership. Specifically, DVD messages were tailored to address the specific cancer screening needs of each user and included messages delivered by community members to address the unique barriers identified by each participant. The tailoring process required women to answer several questions using the remote control requiring active engagement of the user while viewing the entire DVD. Finally, women assigned to the DVD+PN group were reminded to view the DVD by navigators, given time to review the DVD if needed, and called back at a later time to complete navigation.

Patient navigation has been widely adopted in recent years and found to be highly effective in promoting cancer screening uptake [17, 18]. A comprehensive review of the efficacy and cost-effectiveness of PN programs showed positive outcomes, specifically increased uptake and adherence to cancer screening [19]. Recent reviews of studies testing interventions to increase BC and CC screening among rural women showed that PN is effective [20, 21]. Details about the reach, uptake, and satisfaction with navigation, however, were limited in these reviews. Falk made a strong case for the use of social workers as navigators which were employed in our study [20].

Table 6 Navigator encounter and time data ($n = 276$ patients in DVD+PN group who completed the process interview)

Characteristic	$n = 276^1$
Total number of contacts per participant by navigator	
Mean (SD)	22.8 (14.3)
Median (IQR)	20.0 (11.0, 32.0)
Range	2.0, 73.0
Total number of telephone contacts per participant by navigator	
Mean (SD)	15.2 (10.3)
Median (IQR)	12.0 (8.0, 21.0)
Range	1.0, 48.0
Total number of U.S. mail contacts per participant by navigator	
Mean (SD)	5.3 (3.2)
Median (IQR)	5.0 (3.0, 7.0)
Range	1.0, 17.0
Total number of email contacts per participant by navigator	
Mean (SD)	5.0 (6.3)
Median (IQR)	2.0 (1.0, 6.0)
Range	1.0, 35.0
Total number of text contacts per participant by navigator	
Mean (SD)	1.0 (NA)
Median (IQR)	1.0 (1.0, 1.0)
Range	1.0, 1.0
Number of encounters per participant	
0 Navigator encounters	13 (4.7%)
1 or more navigator encounters	263 (95.3%)
Number of encounters per participant	
Mean (SD)	4.0 (2.4)
Median (IQR)	4.0 (2.0, 5.5)
Range	1.0, 14.0
Median encounter length per participant (minutes)	
<5	51 (19.4%)
5–14	177 (67.3%)
15–29	34 (12.9%)
30–44	1 (0.4%)
45–60+	0 (0.0%)
Total encounter time per participant (minutes)	
Mean (SD)	22.2 (21.1)
Median (IQR)	16.0 (8.0, 26.5)
Range	1.0, 136.0
Median coordinating time per participant (minutes)	
<5	84 (31.9%)
5–14	147 (55.9%)
15–29	30 (11.4%)
30–44	2 (0.8%)
45–60+	0 (0.0%)
Total coordinating time (minutes)	
Mean (SD)	21.7 (14.0)
Median (IQR)	18.0 (15.0, 25.0)
Range	1.0, 102.0

¹ n (%).

In the current study, patient navigators encouraged women to view the DVD (if they had not already done so), assessed their knowledge about the screening(s) for which they were not UTD, and addressed barriers to getting screened. Almost all (98.9%) women assigned to receive the PN intervention

remembered receiving a call from the navigator and 98% reported talking with the navigator. The ability of navigators to reach participants by phone in this study exceeded those in other studies [22, 23]. Reasons for the success of navigators in this study included their experience navigating participants in previous cancer screening intervention studies, their understanding of the culture of rural women since they are residents of rural counties themselves, and their persistence because of their belief that they are helping other women. Navigators made 10 attempts to reach participants and varied those attempts across calls, texts, and emails as well as days, evenings, and weekends. If navigators did not reach the participant after 10 attempts, a letter with the navigator's contact information was mailed to the participant stating the navigator was trying to reach them and asked for a call back. Finally, most women had received and viewed the DVD prior to being contacted by the navigator which may have contributed to their acceptance of navigation.

In a trial showing navigators were effective at promoting BC, CC, and CRC screening among 792 patients in a primary care practice network who were overdue for screening, 151 (19%) patients assigned to the intervention could not be reached despite an average of 3.3 attempts [22]. Myers and colleagues tested a navigation intervention to increase CRC screening and reported that the navigator was unable to reach 31 (16%) patients assigned to receive navigation [23].

Consistent with most studies, the majority of participants reported being highly satisfied with navigation and the services navigators provided [24–26]. Navigators made an average number of 22.8 contacts with participants including communication by phone, email, U.S. mail, and text. Navigators had an average of four encounters per participant, spending an average of 22 minutes in total encounter time with participants. Navigators also spent an average of 22 minutes on coordinating activities on behalf of participants.

In this study, barriers discussed by navigators with participants were fairly consistent across types of screening and included screening not being a priority/no symptoms, provider/health care system barriers, lack of knowledge, too much bother/forgetfulness, and other health problems/disability. Common barriers to CC screening were slightly different and included perceptions of not being at risk for CC—a belief that may be attributed to several factors. Older women enrolled in the study who had a hysterectomy were no longer at risk for CC. In addition, like most cancers, it is a common belief that one is not at risk for that cancer if they have no family history of the disease. Barriers addressed in this study were similar to those reported in a national study of patient barriers identified by 437 navigators employed in two large federally-funded cancer screening programs. Barriers to BC, CC, and CRC screening were similar and included: (i) lack of knowledge about cancer, cancer screening procedures, and the benefits of screening; (ii) low motivation to get screened; (iii) transportation; and (iv) health insurance [27].

Limitations

Several limitations should be considered when interpreting results. First, participants in this study reflected the population of rural women in Ohio and Indiana; they were primarily White, married, well-educated, and had health insurance. Rural women of other races who are less educated and under- or uninsured may have responded differently to the DVD or

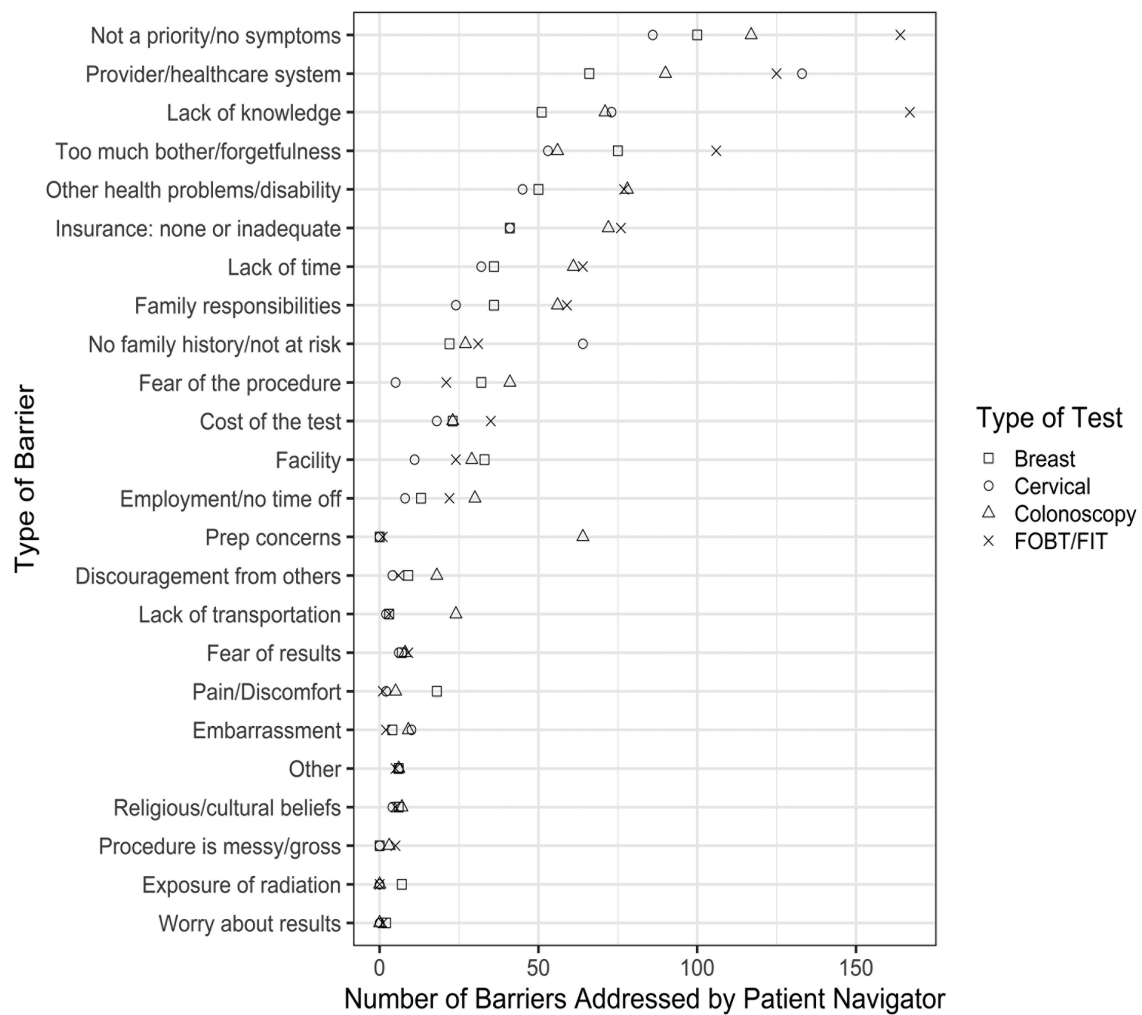


Figure 1 Number of barriers addressed by navigators by type of screening test. *Type of barrier on y-axis is sorted according to total number of times each type was checked for all four tests (Breast + Cervical + Colonoscopy + FOBT/FIT) with greatest number at the top of the graph and smallest number at the bottom

PN interventions. Second, while process data were collected from 93% of participants who viewed the DVD and 98% who spoke with the navigator, we were unable to reach all who were randomized to receive these interventions to assess receipt, uptake, and satisfaction. Of 770 participants assigned to receive the interventions, 542 (70.4%) were reached to complete the process interview and provided data for this analysis. Although satisfaction with both DVD and PN was high, the ability to implement either into clinical practice has yet to be tested. Additionally, while the DVD was relatively inexpensive to deliver, the cost of development was substantial and changes in guidelines for screening now necessitate changes to the DVD content. In a similar manner, satisfaction with PN was high but the feasibility of a busy clinic supporting at least four or more navigation calls for each woman who need cancer screening needs to be explored.

Conclusion/Implications

The current process evaluation provided important data regarding the reach/receipt, uptake, and satisfaction with both behavioral interventions to promote BC, CC, and CRC

screening among rural women who were not UTD with at least one screening test. Process evaluation provides important information to determine the reach and extent a behavioral intervention was implemented as intended, the quality, relevance, and acceptability of the intervention's content among participants, and identifies areas for improvement. These issues are critical to understand the results of interventions tested in randomized controlled trials and for dissemination of effective trials.

Process evaluation is often overlooked when planning and implementing health promotion interventions because it can be tedious, time-consuming, incurs additional cost, and requires additional record-keeping. However, it often provides clues about why an intervention did or did not produce the desired behavioral change. Future investigators who are planning clinical trials need to include a comprehensive process evaluation so that implementation and fidelity of the intervention are monitored since these factors influence the outcome of every intervention trial. Process evaluation will support development of future interventions that are acceptable to participants which may increase intervention effects.

Table 7 Frequency of barriers addressed by navigators by screening tests (among 1281 patient-navigator encounters for patients in DVD+PN group who talked with a navigator)

Barrier category	BC Screening	CC Screening	CRC Screening: colonoscopy	CRC Screening: stool test	Total
Not a priority/no symptoms	100	86	117	164	467
Provider/healthcare system (lack of provider, no recommendation, mistrust, discrimination)	66	133	90	125	414
Lack of knowledge	51	73	71	167	362
Too much bother/forgetfulness	75	53	56	106	290
Other health problems/disability	50	45	78	77	250
Insurance: none or inadequate	41	41	72	76	230
Lack of time	36	32	61	64	193
Family responsibilities	36	24	56	59	175
No family history/not at risk	22	64	27	31	144
Cost of the test	23	18	23	35	99
Fear of the procedure	32	5	41	21	99
Facility (distance, unfamiliar, long wait for appointment)	33	11	29	24	97
Employment/no time off	13	8	30	22	73
Prep concerns	0	0	64	1	65
Discouragement from others	9	4	18	6	37
Lack of transportation	3	2	24	3	32
Fear of results	7	6	8	9	30
Pain/discomfort	18	2	5	1	26
Embarrassment	4	10	9	2	25
Other	6	6	6	5	23
Religious/cultural beliefs	6	4	7	5	22
Procedure is messy/gross	0	0	3	5	8
Exposure to radiation	7	0	0	0	7
Worry about results	2	0	0	1	3
Totals	640	627	895	1009	3171

BC, breast cancer; CC, cervical cancer; CRC, colorectal cancer.

Conflict of Interest

EP reports being the principal investigator on grants to The Ohio State University from Pfizer, Merck Foundation, Guardant Health, and Genentech, not related to this research. She is also an Advisory Board Member for Glaxo Smith Kline. The remaining authors have no relevant financial or non-financial interests to disclose.

Funding

National Cancer Institute (R01 CA196243), Recruitment, Intervention and Survey Shared Resource at The Ohio State University Comprehensive Cancer Center (P30 CA016058), and the Ohio State University CTSA (UL1TR002733) from the National Center for Advancing Translational Sciences. Funding sponsors did not have any role in the study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.

Human rights

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or com-

parable ethical standards. This study was approved by The Ohio State University and Indiana University Institutional Review Boards. This article does not contain any studies with animals performed by any of the authors.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Study registration

This study is registered at www.clinicaltrials.gov NCT02795104 as of October 2016.

Analytic plan pre-registration

The analysis plan was registered prior to beginning data collection at www.clinicaltrials.gov NCT02795104 as of October 2016.

Data Availability

De-identified data from this study are not available in a public archive. De-identified data will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.

Analytic code availability

Analytic code used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author.

Materials availability

Materials used to conduct the study are not publicly available

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