Comparative Effectiveness of Two Interventions to Increase Colorectal Cancer Screening for Those at Increased Risk Based on Family History: Results of a Randomized Trial

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ABSTRACT

Background: First-degree relatives (FDRs) of patients with colorectal cancer are at risk for colorectal cancer, but may not be up to date with colorectal cancer screening. We sought to determine whether a one-time recommendation about needing colorectal cancer screening using patient navigation (PN) was better than just receiving the recommendation only.

Methods: Participants were FDRs of patients with Lynch syndrome-negative colorectal cancer from participating Ohio hospitals. FDRs from 259 families were randomized to a website intervention (528 individuals), which included a survey and personal colorectal cancer screening recommendation, while those from 254 families were randomized to the website plus telephonic PN intervention (515 individuals). Primary outcome was adherence to the personal screening recommendation (to get screened or not to get screened) received from the website. Secondary outcomes examined who benefited from adding PN.

Results: At the end of the 14-month follow-up, 78.6% of participants were adherent to their recommendation for colorectal cancer screening with adherence similar between arms ($P = 0.14$). Among those who received a recommendation to have a colonoscopy immediately, the website plus PN intervention significantly increased the odds of receiving screening, compared with the website intervention (OR: 2.98; 95% confidence interval, 1.68–5.28).

Conclusions: Addition of PN to a website intervention did not improve adherence to a colorectal cancer screening recommendation overall; however, the addition of PN was more effective in increasing adherence among FDRs who needed screening immediately.

Impact: These findings provide important information as to when the additional costs of PN are needed to assure colorectal cancer screening among those at high risk for colorectal cancer.

Introduction

Colorectal cancer is the third most common type of cancer and second-leading cause of cancer-related death among men and women in the United States (1). The best way to prevent colorectal cancer is adherence to screenings, such as colonoscopy, which can detect and remove precancerous lesions prior to cancer development (1). According to the U.S. Preventive Services Task Force, an individual at average-risk for colorectal cancer are at risk for colorectal cancer, but may not be up to date with colorectal cancer screening. We sought to determine whether a one-time recommendation about needing colorectal cancer screening using patient navigation (PN) was better than just receiving the recommendation only.

Methods: Participants were FDRs of patients with Lynch syndrome-negative colorectal cancer from participating Ohio hospitals. FDRs from 259 families were randomized to a website intervention (528 individuals), which included a survey and personal colorectal cancer screening recommendation, while those from 254 families were randomized to the website plus telephonic PN intervention (515 individuals). Primary outcome was adherence to the personal screening recommendation (to get screened or not to get screened) received from the website. Secondary outcomes examined who benefited from adding PN.

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55 or two relatives diagnosed with colorectal cancer) adhered to colorectal cancer screening guidelines (7). Results of these studies indicate an opportunity to increase screening adherence among FDRs of patients with colorectal cancer.

Previous interventions have demonstrated effectiveness in increasing adherence to colorectal cancer screening among patients with colorectal cancer and/or FDRs. Prior interventions have used mailed print materials demonstrating the importance of colorectal cancer screening with or without telephone counseling (9–12). These interventions reported increased colorectal cancer screening among individuals who received tailored print or telephone interventions (9, 10, 12–16). Patient navigation (PN) is an established intervention for promoting cancer screening (17–20); however, there are costs associated with PN over nonperson intensive interventions like printed material (21). Moreover, not all patients need or use PN when offered (22, 23). Newer interventions using Web-based technology (24–27) also show promise for delivering education about the need for screening at lower cost (28). PN has only been tested in one study among FDRs of patients with colorectal cancer to improve colorectal cancer screening (12), but not with a website delivering a personalized prescription for screening. We assessed the comparative effectiveness of a website-only intervention or website plus PN intervention on adherence to colorectal cancer screening among FDRs of patients with colorectal cancer in Ohio. If PN does not add any benefit to improve colorectal cancer screening in this high risk population, then the cheaper option could be easily implemented. It is also important to understand who benefits from the addition of PN in terms of improved colorectal cancer screening.

Materials and Methods
Study setting and enrolment
The Adherence to Colorectal Cancer Screening (ACCS) study is part of the larger Ohio Colorectal Cancer Prevention Initiative (OCCPI). The OCCPI was established to decrease colorectal cancer incidence in Ohio by identifying patients with hereditary predisposition [statewide Universal Screening for Lynch syndrome (USLS study), increasing colonoscopy adherence for FDRs of patients with colorectal cancer (ACCS study) and encouraging future research through the creation of a biorepository]. Ohio was an ideal site for the OCCPI as it has higher incidence and mortality from colorectal cancer compared with national rates (www.cdc.gov/uscs). Methods for the overall OCCPI study have been published (29) and are only briefly described here. Participants for the ACCS study were identified through the OCCPI as follows.

Patients diagnosed with colorectal cancer (probands) at one of 51 participating hospitals in Ohio from 2013 to 2016 were eligible to be recruited to the USLS study. Patients with colorectal cancer in the USLS study all received tumour screening for Lynch syndrome, and follow-up genetic testing if they met certain criteria (abnormal tumor screening, diagnosed <50, FDR with colorectal cancer or endometrial cancer, or had synchronous or metachronous colorectal cancer or endometrial cancer). Probands and their FDRs were excluded from ACCS if they were not between the ages of 25–75 years, were pregnant, incarcerated, cognitively impaired, or had been diagnosed with inflammatory bowel disease, Crohn disease, colitis, or any hereditary cancer syndrome. Because of different screening recommendations for patients with colorectal cancer and their FDRs with Lynch syndrome versus those without Lynch syndrome (6), only FDRs of patients with colorectal cancer in USLS who screened negative for Lynch syndrome and participated in ACCS are included in this report.

Participants were enrolled in ACCS from 2013 to 2017, and the last exit interview for participants was completed in January 2018. The trial was completed as planned after the 5-year time period for study collection had ended. A total of 1,643 patients with colorectal cancer (probands) were referred to the study from the USLS arm (Fig. 1), of which 919 (56%) consented to participate in ACCS and completed the baseline survey. A total of 513 probands were enrolled who provided at least one FDR (Fig. 1). These probands referred a total of 2,403 FDRs, of which 484 were ineligible and 865 were unable to be contacted or refused, leaving 1,054 eligible FDRs (55% of total eligible) who consented to participate in ACCS. Ten FDRs did not receive a recommendation via the website due to incomplete data provided, and one FDR received an incorrect message due to an error in the recording of age. These 11 participants were eliminated from the analyses, leaving 1,043 FDRs across 513 unique families. There was very low risk for harm in this intervention and no adverse events were reported. This study was conducted in accordance with the criteria set by the declaration of Helsinki and each participant provided written informed consent. The study was approved by the Ohio State University (OSU) Institutional Review Board (Columbus, OH).

Randomization
A nested cohort group-randomized trial (GRT) design was utilized with the unit of randomization being the proband and their FDRs. This design was used to eliminate contamination of the intervention effect within families by assigning participants who were members of the same family to the same study arm. Families were randomized 1:1 to either the website intervention or website plus PN intervention. Of 513 families, 259 families (528 FDRs) were randomized to the website intervention arm, while 254 families (515 FDRs) were randomized to the website plus PN intervention arm. Randomization was also stratified by hospital and utilized a permuted block randomization scheme with block sizes of two and four. A centralized Web-based system at the OSU was used for all randomization assignments. Whereas patients and study staff allocating participants to each study group were aware of the study arm, outcome assessors and investigators were kept blinded to the allocation.

Website intervention
All participants received a call from study staff for consent and to complete a baseline survey. Following this, they received a link to a website that collected demographic characteristics and health-related characteristics (e.g., colorectal cancer screening history, personal cancer history, and family history of cancer). If a participant did not have internet access, an appointment was scheduled to complete the Web questions over the phone with study interviewers. If the participant preferred that interview staff provide assistance, they could complete the website questions while on the baseline call. If unreachable by phone, participants were sent a letter asking them to contact the ACCS via a toll-free phone number.

Following completion of the Web survey, a personal colorectal cancer screening recommendation document was generated that indicated when a colonoscopy was due (at the present time or later), based on the NCCN guidelines version 2.2012 (6). The personal screening recommendation was based on participant’s age, the age of the youngest colorectal cancer diagnosis among FDRs, history of most recent colorectal cancer screening, and personal history of colorectal cancer, all based on information in the database about both the proband (age at diagnosis) and the FDR (from the Web survey). The recommendation document also included suggestions for healthy behaviors, such as a healthy diet, sufficient sleep, daily exercise,
smoking cessation, and a recommendation to talk to family members about the importance of colorectal cancer screening. The recommendation linked to information regarding colorectal cancer from websites such as the NCI, the American Cancer Society, and the AGA, and participants were urged to share the recommendation with their primary care provider. Participants could access the recommendation document online and/or have it mailed/emailed to them.

**Website plus patient navigation intervention**

In addition to the website, participants assigned to the combined intervention also received access to telephonic PN. Navigators addressed individual barriers to adhering to the personal recommendation, as is the process of PN (30). Navigators called participants 1 month after the receipt of the website recommendation to assess barriers to screening, provide counseling to remove these barriers, and assist participants with scheduling issues for those who needed a colonoscopy. Navigators encouraged participants to talk to their doctor about scheduling a colonoscopy. Following this initial call, navigators periodically followed-up with participants to check on the status of screening and to provide additional assistance and support as needed. For participants whose personal recommendation did not recommend immediate colorectal cancer screening, on the initial call, navigators suggested discussing results with their doctor and reminded participants of the importance of being screened and completing screenings according to the NCCN guidelines. If participants did not visit the website within 1 month of completing the baseline survey, a navigator called the participant to follow-up, regardless of need for screening. Overall, navigators provided follow-up calls based on each participants barriers and needs, as is customary (30).

**Primary outcome**

The primary outcome was adherence to the personal recommendation received from the website (where colorectal cancer screening was either recommended at the present time or no screening was recommended at the present time) over the 14-month follow-up period for each participant. This time period was used to allow time to complete the screening, given lag time in scheduling. For participants who were within the recommended colorectal cancer screening guidelines at the time of website completion, adherence was defined as receiving no further screening in the 14 months follow-up period. For participants not within guidelines at the time of website completion, adherence was defined as receiving a colonoscopy within the 14 months follow-up period. All other participants were classified as nonadherent.

![Figure 1. Recruitment and inclusion of participants in the ACCS trial.](#)
by medical record review (MRR), which was obtained on 71.7% of participants; however, as described below, multiple imputation was used to impute missing outcome data to allow for inclusion of all participants in the analysis. The primary reasons for missing MRR were refusal to sign the MRR release (n = 172) and clinic noncompliance with the request (n = 95).

**Statistical analyses**

Evaluation of the primary outcome of adherence to the personal recommendation regarding colorectal cancer screening (to get a colonoscopy at the present time vs. a test not needed) by 14 months was achieved through analysis of the primary outcome included study arm as the only predictor. Subsequent multivariable analyses explored factors that modified or confounded the effect of the addition of PN in an effort to determine who might have benefited from PN. Potential factors included the interaction between study arm and whether the personal recommendation indicated that the participant was due for a colonoscopy at the present time, as well as covariates that resulted in a 15% or greater change in the observed intervention effect. All analyses were conducted in SAS v9.4 (SAS Institute).

**Results**

Descriptive characteristics of participants are listed in Table 1. A majority of the participants were female (56.7%), white (94.8%), and married or living with a partner (74.8%). Nearly all (95.2%) had some form of health insurance, and most participants (92.0%) had a colonoscopy. The reason for possible over-screening was indicated by medical record review (MRR), which was obtained on 71.7% of participants; however, as described below, multiple imputation was used to impute missing outcome data to allow for inclusion of all participants in the analysis. The primary reasons for missing MRR were refusal to sign the MRR release (n = 172) and clinic noncompliance with the request (n = 95).

**Table 1. Characteristics of study participants by study arm.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Website only (n = 528)</th>
<th>Website + PN (n = 515)</th>
<th>Total (N = 1,043)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Age (mean [SD])</td>
<td>51.4 (12.8)</td>
<td>52.1 (13.6)</td>
<td>51.7 (13.2)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>262 (49.6)</td>
<td>190 (36.9)</td>
<td>452 (43.3)</td>
</tr>
<tr>
<td>Female</td>
<td>266 (50.4)</td>
<td>325 (63.1)</td>
<td>591 (56.7)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>489 (92.6)</td>
<td>500 (97.1)</td>
<td>989 (94.8)</td>
</tr>
<tr>
<td>Black</td>
<td>23 (4.4)</td>
<td>7 (1.4)</td>
<td>30 (2.9)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (3.0)</td>
<td>8 (1.6)</td>
<td>24 (2.3)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or living with a partner</td>
<td>400 (75.8)</td>
<td>379 (73.7)</td>
<td>779 (74.8)</td>
</tr>
<tr>
<td>Divorced or widowed</td>
<td>78 (14.8)</td>
<td>75 (14.6)</td>
<td>153 (14.7)</td>
</tr>
<tr>
<td>Never married</td>
<td>50 (9.5)</td>
<td>60 (11.7)</td>
<td>110 (10.6)</td>
</tr>
<tr>
<td>Insurance status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not insured</td>
<td>24 (4.6)</td>
<td>26 (5.1)</td>
<td>50 (4.8)</td>
</tr>
<tr>
<td>Public insurance</td>
<td>124 (23.6)</td>
<td>136 (26.6)</td>
<td>260 (25.1)</td>
</tr>
<tr>
<td>Private insurance</td>
<td>378 (71.9)</td>
<td>349 (68.3)</td>
<td>727 (70.3)</td>
</tr>
<tr>
<td>Household income</td>
<td>$40,000–$79,999</td>
<td>101 (20.0)</td>
<td>99 (20.6)</td>
</tr>
<tr>
<td>Employment status</td>
<td>$80,000+</td>
<td>173 (34.3)</td>
<td>149 (31.0)</td>
</tr>
<tr>
<td>Work full or part time</td>
<td>231 (45.7)</td>
<td>233 (48.4)</td>
<td>464 (47.1)</td>
</tr>
<tr>
<td>Unemployed/disabled/student</td>
<td>371 (70.5)</td>
<td>331 (64.3)</td>
<td>702 (76.3)</td>
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<tr>
<td>Retired</td>
<td>93 (17.6)</td>
<td>115 (22.3)</td>
<td>208 (19.9)</td>
</tr>
<tr>
<td>Educational attainment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or less</td>
<td>139 (26.3)</td>
<td>150 (29.1)</td>
<td>289 (27.7)</td>
</tr>
<tr>
<td>Some college</td>
<td>151 (28.6)</td>
<td>121 (23.5)</td>
<td>272 (26.1)</td>
</tr>
<tr>
<td>College degree or higher</td>
<td>238 (45.1)</td>
<td>244 (47.4)</td>
<td>482 (46.2)</td>
</tr>
<tr>
<td>Relationship to proband</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>263 (49.8)</td>
<td>229 (44.5)</td>
<td>492 (47.2)</td>
</tr>
<tr>
<td>Sibling</td>
<td>233 (44.1)</td>
<td>234 (45.4)</td>
<td>467 (44.8)</td>
</tr>
<tr>
<td>Child</td>
<td>32 (6.1)</td>
<td>52 (10.1)</td>
<td>84 (8.1)</td>
</tr>
<tr>
<td>Perceived likelihood of getting CRC in a lifetime</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not likely at all</td>
<td>174 (33.0)</td>
<td>176 (34.3)</td>
<td>350 (33.7)</td>
</tr>
<tr>
<td>Likely or very likely</td>
<td>277 (52.6)</td>
<td>274 (53.4)</td>
<td>551 (53.0)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>77 (14.6)</td>
<td>80 (15.5)</td>
<td>157 (15.1)</td>
</tr>
<tr>
<td>Former</td>
<td>157 (29.7)</td>
<td>149 (28.9)</td>
<td>306 (29.3)</td>
</tr>
<tr>
<td>Never</td>
<td>294 (55.7)</td>
<td>286 (55.5)</td>
<td>580 (55.6)</td>
</tr>
<tr>
<td>Never</td>
<td>294 (55.7)</td>
<td>286 (55.5)</td>
<td>580 (55.6)</td>
</tr>
</tbody>
</table>

Note: Descriptive statistics from complete case analyses. Abbreviation: CRC, colorectal cancer.

In an effort to determine who benefited from the addition of PN, we explored whether there was a differential effect by study arm and the personal screening recommendation received. Among participants with complete MRR who received a recommendation to not get a colonoscopy, adherence was similar across study arms (90.7% in the website intervention arm vs. 88.8% in the website plus PN intervention arm). However, there was much greater adherence when PN was included.
difference for participants who received a recommendation to get a colonoscopy, as 29.8% of those in the website intervention arm were classified as adherent compared with 52.8% of those in the website plus PN intervention arm (see Fig. 2). Results from a GEE model using the multiple imputations that included effects for study arm, the recommendation received and the interaction of the two indicated a significant interaction effect \((P = 0.0006)\). Model-estimated ORs showed a similar pattern to the complete case analysis with an OR of 0.79 (95% CI, 0.47–1.33; \(P = 0.37\)) for website plus PN intervention versus website intervention among those not recommended to receive a colonoscopy at the present time and an OR of 2.98 (95% CI, 1.68–5.28; \(P = 0.0002\)) among those with a recommendation for a colonoscopy at the present time. No additional interactions or confounders were identified.

In assessing intervention fidelity, all participants received a personalized screening recommendation from the website (either to be screened or not to be screened immediately). Of those randomized to the website plus PN intervention, 88.9% \((n = 458)\) spoke with the navigator \((8 \text{ refused and } 49 \text{ were unable to be contacted by the navigator). Of those who spoke with the navigator, } 45.0\% \((n = 206)\) received resources from the navigator \((\text{fact sheets, booklets, and Web links}). Most participants \((74.8\% )\) had only one encounter with the navigator \((\text{maximum: } 10); \text{ however, the majority of those who needed a colonoscopy had more than one encounter } (68.1\% ) \text{ for an average of three encounters.}

As is typical with PN, barriers to adherence to the recommendation were assessed and then the navigator addressed each barrier listed. Most participants did not report a barrier to following the screening recommendation \((77.7\% ), \text{ while 16.4\% reported 1–3 barriers and 5.9\% reported four or more barriers (range: 0–8). The most commonly reported barriers to screening were: not a priority/too much bother/ don’t want to } (45.1\% ), other priorities or health issues \((33.3\% ), \text{ not enough time } (32.4\% ), \text{ doctor never recommended or received different colorectal cancer screening recommendation } (24.5\% ), \text{ and not at risk or not necessary due to no problems } (23.5\% ). Navigator response to barriers included support \((53\% ); \text{ encouragement and helping to understand why it is important to get tested, potential outcomes); education (43.2\% ; what the tests are, what to expect, and what questions to ask); and referral (3.3\% ; to providers in the area and what to ask for and help with scheduling).
surveillance guidelines. A recent study found that while 84%–88% of digestive disease specialists reported that they were confident in recalling colorectal cancer surveillance and screening guidelines, only 22%–37% could accurately identify the factors that determine screening age of onset and surveillance interval and questions involving four clinical vignettes involving screening and surveillance (34).

The main limitation includes the smaller sample size compared with our original recruitment goal. Out of 919 probands that consented to participate in ACCS and completed the baseline survey, 1,054 eligible FDRs were referred and participated. This equated to approximately one FDR per proband rather than the four we estimated. Participants in our study were mostly white, college educated, and had health insurance, limiting generalizability of these results to underserved, minority, or low socioeconomic populations. Thus, the interventions described in this study should be tested in more diverse populations. For example, other studies have shown the benefit of PN in increasing screening in minority and low-income populations (23, 35), thus PN might be an ideal way to improve screening in high-risk family members in these populations. Moreover, complete MRR was assessed for approximately 70% of FDR participants, suggesting the potential for selection bias if participants for whom we were unable to obtain medical records were somehow different from those for whom we could obtain medical record data. We did, however, use imputation to address missing data.

Despite these limitations, our study has several strengths. The GRT design as well as MRR of colonoscopy screening provided rigor to the study design and reduced the risk of potential bias. Moreover, the use of telephonic PN allowed for consistent and timely implementation of the intervention, that is, 89% of participants in that arm received a baseline call from the navigator. Furthermore, PN was accessible to large geographic regions for the FDRs, from 34 states across the United States, plus Washington D.C. Data from our assessment of intervention feasibility collected important information on the actions of the navigator as well as barriers to screening experienced by FDRs. This information is important to those who wish to replicate these interventions.

Conclusions

Although initial results revealed no benefit with the addition of PN to the website intervention on adherence to screening recommendations (need a colonoscopy now or do not need one now), subsequent analyses of who benefited from the addition of PN indicated that the addition of telephonic PN to the website was more effective than the website alone on increasing adherence to colonoscopy among FDRs who needed a colonoscopy immediately, potentially reducing future incidence of colorectal cancer among those at increased risk.

Disclosure of Potential Conflicts of Interest

E.D. Paskett reports receiving a commercial research grant from Merck and has ownership interest (including patents) in Pfizer. H. Hampel is a scientific advisory board member for Invitae Genetics and Genome Medical, a medical advisory board member for Progenex, and a consultant for 23andMe and reports receiving other commercial research support from Myriad Genetic Laboratories, Inc. No potential conflicts of interest were disclosed by the other authors.

Authors’ Contributions

Conception and design: E.D. Paskett, B.M. Bernardo, M.L. Katz, P.L. Reiter, J.M. Oliveri, H. Hampel


Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): E.D. Paskett, J.M. Oliveri, C.R. DeGraffenreid, R. Pearlman

Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): E.D. Paskett, B.M. Bernardo, G.S. Young, P.L. Reiter, H. Hampel

Writing, review, and/or revision of the manuscript: E.D. Paskett, B.M. Bernardo, G.S. Young, M.L. Katz, P.L. Reiter, J.M. Oliveri, C.R. DeGraffenreid, D.M. Gray, R. Pearlman, H. Hampel

Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases): E.D. Paskett, B.M. Bernardo, C.M. Tatum


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References

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