

A LONGITUDINAL ANALYSIS TO COMPARE A TAILORED WEB-BASED
INTERVENTION AND TAILORED PHONE COUNSELING TO USUAL CARE FOR
IMPROVING BELIEFS OF COLORECTAL CANCER SCREENING

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An analysis of longitudinal data collected about beliefs regarding colorectal cancer (CRC) screenings at three-time points was analyzed to determine whether the beliefs improved from either the Web-Based, Phone-Based, or Web + Phone interventions compared to Usual Care. A mixed linear model adjusting for baseline and controlling for covariates was used to determine the effects of the intervention; Web-Based intervention was the most efficacious in improving beliefs, and phone intervention was also efficacious for several beliefs, compared to usual care.

Patrick Monahan, PhD, Chair

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Chapter 1

INTRODUCTION

There is substantial evidence that colorectal and breast screenings can significantly reduce cancer related mortality. Five-year survival is 90% for colorectal cancer (CRC) when diagnosed while still localized (i.e., confined to the wall of the bowel), but only 68% for regional disease (i.e., disease with lymph node involvement), and only 10% if distant metastases are present (Levin, et al., 2008). Continued advances in cancer research, detection, and treatment have resulted in a decline in both incidence and death rates for all cancers. The Cancer objectives for Healthy People 2020 support monitoring trends in cancer incidence, mortality, and survival to better assess the progress made toward decreasing the burden of cancer in the United States (Healthy People 2020, 2018). It is hypothesized that colorectal and breast cancer screening outcomes could be improved through a randomized intervention trial. This study was supported by the National Cancer Institute and was developed to increase colorectal and breast cancer screening using tailored Web and Phone-based interventions for women over the age of fifty. This study was approved by the Institutional Review Board at Indiana University and community sites under Principle Investigator Victoria Champion. This study is registered with the clinical trials identifier NCT03279198 <https://clinicaltrials.gov/show/NCT03279198>.

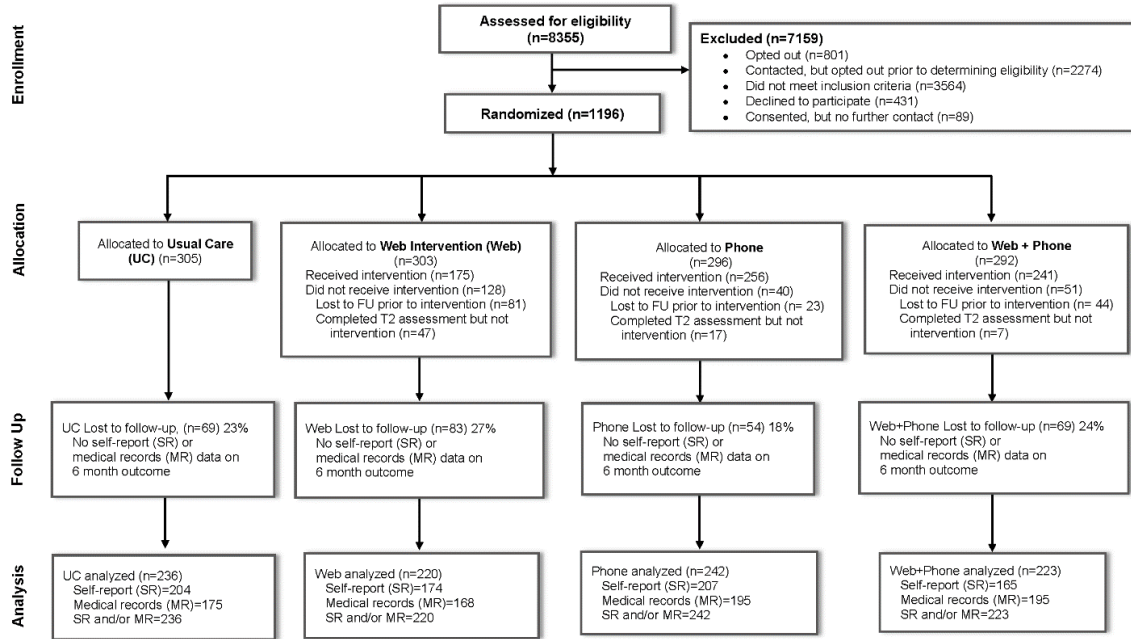
Randomized clinical studies show behavioral interventions, including mailed invitations, telephone counseling, navigation, and a combination of patient navigation and telephone support, significantly increase CRC screening compared to a patient's usual care (Jerant,

et al., 2013). Furthermore, tailoring to demographic and belief variables (e.g., perceived risk, perceived benefits, perceived barriers, self-efficacy, fatalism, and fear) increases relevance of the intervention messages, thereby increasing intervention effects (Lustria, et al., 2016). When comparing tailored messages to non-tailored approaches or to motivational interviewing, some research has found tailored messages significantly improve cancer-screening behaviors (Menon, et al., 2011). If a web-based approach were efficacious, it could potentially decrease cost and increase dissemination for cancer screening interventions.

DESIGN

A prospective, randomized 2 x 2 factorial design was used to compare the impact of three tailored interventions to Usual Care on CRC screening adherence and the secondary outcome of stage-of-change to complete CRC screening. A total of 1196 woman were randomized to four groups: 1) Usual Care, 2) tailored Web-based, 3) tailored Phone counseling, or 4) a Web-based + Phone counseling intervention. The Consort Diagram is illustrated in Figure 1. The randomization was performed in a Microsoft SQL database, using SQL random ordering functions, without additional stratification.

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram



OUTCOMES

Outcomes were completion of CRC screening by stool test, colonoscopy, either screening test (i.e., Any CRC), or a risk-appropriate screening test. Risk-appropriate CRC screening was defined as completion of the appropriate test based on the level of risk conferred by family history. For participants who had more than one first-degree relative who was diagnosed with CRC or a first-degree relative diagnosed younger than age 60, colonoscopy is the most appropriate screening test. This study also assessed mammography screening outcomes; however, this thesis is focused only on the knowledge and beliefs that are relevant to the CRC outcomes. A total of 275 (23%) were lost to follow-up. The Web group had the highest attrition (27%) and the Phone group had the lowest (18%). For analyses, we used a best estimate outcome data set which combined both self-report and medical

record data. We counted the screening as positive (i.e., yes) if either self-report or medical record data indicated a screening test. This best-estimate data set allowed us to include women who did not have six-month self-report but had medical record data or conversely allowed use of self-report data if medical records data were not available. This thesis focuses on testing the efficacy of interventions to improve the knowledge and beliefs that should theoretically increase CRC screening.

INTERVENTIONS AND TAILORING

Tailoring focused on key demographic variables (e.g., age, race) and belief variables (mediators) that were theoretically linked to screening behavior. An algorithm embedded in the program directed women at higher than average risk to an intervention that encouraged colonoscopy while women at average risk could select either stool test or colonoscopy followed by a program consistent with their preferred test. The tailored Web program was developed such that a woman's demographic and belief responses (queried throughout the program) triggered an algorithm which selected and delivered messages tailored to each woman's response. Constructs used for tailoring included age, race, family history of colon cancer, knowledge and beliefs about colon cancer and CRC screening. Messages were developed and refined from previous research using similar tailoring. For example, if a woman did not perceive a personal risk for CRC or benefits of screening, messages were delivered to reinforce the fact that CRC can happen to anyone and that screening identifies cancer early when treatment is most successful. Women were able to identify up to three personal barriers and for each barrier identified, a message suggesting

ways to overcome the barrier. The Web program included graphs, text, videos and animation to reinforce verbal messaging. The Phone Only Intervention consisted of a computer program that was used to structure the content and flow of the telephone counseling session. The trained interventionist queried women throughout the program to tailor the messaging. Messaging was delivered in a conversational way to increase engagement and interest of participants. The computer interface provided structure for discussing content consistent with the message flow in the Web-based program. For people at average risk, the interventionist asks about their preferred tests and if a woman stated stool test, it was mailed to their home. If the woman were at high risk or preferred colonoscopy, a number to schedule the colonoscopy was provided. The mean time for the Phone intervention was 19 minutes. The Web + Phone intervention consisted of the completion of the web program followed within four weeks by Phone counseling. For the Usual Care group, women did not receive an intervention, but depending on location of the family practice site, enrolled women may have received a postcard reminder for cancer screenings from their primary care provider.

Chapter 2

ANALYSIS

Longitudinal data was collected at three-time points throughout the study (baseline, 2 months post-intervention, and 6 months post-intervention). This thesis focuses on nine knowledge and belief response variables related to CRC and its screening: fatalism, fear, susceptibility to colon cancer, benefits to colon cancer screening, barriers to stool test and colonoscopy, and self-efficacy for stool test and colonoscopy. The primary assumptions underlying the analyses performed are that the residuals of the model of interest (which incorporates covariates) are normally distributed, the means of the response variable are linear in the covariates, and the variances and covariances of the data satisfy the assumed covariance structure (Overview: Mixed Procedure, 2018). The restricted maximum likelihood parameter estimation approach (REML) is applied to deal with the bias of regular maximum likelihood estimation (MLE) for the variance parameter in small samples. The distribution of the residuals is assumed to be normal; however, the distribution of the residuals no longer depends on the estimates of the fixed effects, it only depends on the variance components (Kreft & de Leeuw, 1998).

The mixed model approach to the analysis of repeated measurements allows users to model the covariance structure of their data. That is, rather than using a univariate or a multivariate test statistic for analyzing effects (i.e., tests that assume a particular form for the covariance structure), the mixed model approach allows the data to be assessed to determine the appropriate structure. Using the appropriate covariance structure could result in more valid

tests of the repeated measures effects. Common covariance structures are unstructured, compound symmetry, heterogenous compound symmetry, autoregressive, and heterogenous autoregressive.

Chapter 3

RESULTS

Table 1 shows baseline demographics by randomized arm. Random assignment was reasonably successful at balancing the randomized groups on the potentially confounding baseline characteristics. The baseline characteristics that were significantly different between the randomized groups were adjusted for in the multivariable repeated measures mixed linear model, along with other covariates that were theoretically important as potentially confounding variables (i.e., theoretically related to screening behavior).

Table 1: Baseline Characteristics by Randomized Group

Baseline Characteristics Number (%) or Mean (SD)	Total Sample (n=1196)	Web (n=303)	Phone (n=296)	Web+ Phone (n=292)	Usual Care (n=305)	p- value
Doctor or HCP ever suggested you do a stool test? n (%) responding yes	458 (38.3)	120 (39.6)	119 (40.2)	108 (37.0)	111 (36.5)	0.7304
Doctor ever recommended that you have a colonoscopy? n (%) responding yes	785 (65.8)	194 (64.2)	192 (65.1)	201 (68.8)	198 (65.1)	0.6480
Baseline adherence to breast cancer screening	504 (42.1)	123 (40.6)	128 (43.2)	125 (42.8)	128 (42.0)	0.9185
Baseline Colorectal Cancer Screening Stage, n (%) in Contemplation at baseline; (n, % in Precontemplation can be calculated as 100 - % shown below)						
Stool test at home	173 (14.5)	43 (14.2)	44 (14.9)	41 (14.0)	45 (14.8)	0.9894
Colonoscopy	291 (24.3)	79 (26.1)	66 (22.3)	76 (26.0)	70 (22.9)	0.5858
Any Colorectal Cancer Screening	410 (34.3)	107 (35.3)	98 (33.1)	104 (35.6)	101 (33.1)	0.8639
Risk-appropriate Colorectal cancer screening	404 (33.8)	106 (35.0)	98 (33.2)	101 (34.6)	99 (32.5)	0.7062
Age, mean (SD)	58.9 (6.2)	59.3 (6.4)	58.7 (6.0)	58.6 (5.9)	58.9 (6.3)	0.5727

Highest education						0.5279
High school graduate or less	332 (27.8)	79 (26.1)	85 (28.9)	90 (30.8)	78 (25.7)	
Some college	501 (42.0)	137 (45.2)	120 (40.8)	121 (41.4)	123 (40.5)	
4-year college graduate to graduate degree	360 (30.2)	87 (28.7)	89 (30.3)	81 (27.7)	103 (33.9)	
Race						0.0363
Black or African American	124 (10.4)	40 (13.2)	22 (7.4)	36 (12.3)	26 (8.5)	
White or Caucasian	1032 (86.3)	255 (84.2)	269 (90.9)	243 (83.2)	265 (86.9)	
Asian, Pacific Islander, or Other	40 (3.4)	8 (2.6)	5 (1.7)	13 (4.5)	14 (4.6)	
Married or living with a partner	719 (60.4)	182 (60.1)	188 (64.0)	171 (58.8)	178 (58.8)	0.4493
Total combined yearly household income before taxes						0.6973
\$30,000 or less	359 (31.2)	99 (33.9)	82 (28.8)	95 (33.3)	83 (28.6)	
\$30,001 - \$75,000	474 (41.2)	114 (39.0)	124 (43.5)	110 (38.6)	126 (43.5)	
\$75,001 or above	319 (27.6)	79 (27.1)	79 (27.7)	80 (28.1)	81 (27.9)	
In the past year, how many times have you seen your doctor or other HCP? (not counting dentist or eye doctor)						
3 or more times, n (%)	573 (48.3)	167 (55.5)	130 (44.1)	144 (49.5)	132 (44.2)	0.0144
Body Mass Index (BMI)						0.6359
Underweight / Normal	287 (25.0)	70 (24.0)	74 (26.2)	72 (25.9)	71 (24.1)	
Overweight	324 (28.2)	86 (29.5)	82 (29.0)	66 (23.7)	90 (30.5)	
Obese	537 (46.8)	136 (46.6)	127 (44.9)	140 (50.4)	134 (45.4)	
Total number of self-reported health problems, mean (SD)	1.8 (1.7)	2.1 (1.8)	1.7 (1.7)	1.8 (1.6)	1.7 (1.6)	0.0190
Does depression limit your activities? n (%) yes,	99 (8.5)	27 (9.1)	17 (6.0)	37 (12.8)	18 (6.0)	0.0084
Perceived age- adjusted risk for colon cancer, n (%)						0.6297
About the same or not sure	873 (73.0)	216 (71.3)	212 (71.6)	225 (77.3)	220 (72.1)	
Higher risk	82 (6.9)	22 (7.3)	19 (6.4)	17 (5.8)	24 (7.9)	
Lower risk	240 (20.1)	65 (21.4)	65 (22.0)	49 (16.8)	61 (20.0)	

Cancer and Cancer Screening Beliefs						
Fatalism	20.5 (6.9)	20.4 (6.4)	20.9 (7.2)	20.6 (6.8)	20.1 (7.0)	0.6159
Fear	23.0 (7.5)	23.1 (7.5)	23.4 (7.6)	22.9 (7.5)	22.4 (7.3)	0.4497
Susceptibility to colon cancer	6.8 (2.2)	6.8 (2.2)	6.8 (2.2)	6.8 (2.3)	6.8 (2.2)	0.9895
Benefits of colorectal cancer screening	18.1 (3.1)	18.1 (3.1)	18.0 (3.3)	18.0 (3.0)	18.1 (3.1)	0.9260
Barriers to Stool Test	20.1 (5.0)	19.9 (5.3)	20.4 (5.0)	20.1 (5.1)	19.9 (4.6)	0.5577
Barriers to colonoscopy	36.1 (8.7)	36.0 (8.8)	36.6 (9.0)	36.3 (8.9)	35.3 (8.0)	0.2744
Self-efficacy for Stool Test	28.4 (4.8)	28.4 (4.8)	28.7 (4.5)	28.2 (5.3)	28.4 (4.7)	0.5341
Self-efficacy for colonoscopy	36.9 (7.2)	36.7 (7.5)	36.7 (7.2)	36.9 (7.3)	37.3 (6.7)	0.7387
Knowledge for colonoscopy	5.3 (1.9)	5.2 (1.9)	5.3 (1.9)	5.2 (2.0)	5.3 (1.9)	0.8782

In Table 2 the AIC of each covariance structure is shown. Smaller AIC is better. There were minimal differences in AIC between the covariance structures. Therefore, the unstructured covariance matrix was chosen because it is the most conservative structure making no assumptions on the covariance structure and yet yielding similar AIC as other structures. The unstructured covariance specification uses the most parameters but because we were not concerned with losing degrees of freedom, given there are only two-time points for the response measurements (recall, the baseline measure of the outcome is adjusted for as a covariate), the unstructured covariance matrix was selected.

Table 2: AIC of Covariance Structures

	Unstructured	Compound Symmetry	Heterogenous Compound Symmetry	Auto-regressive	Heterogenous Auto-regressive
Fatalism	8413.5	8416.8	8413.5	8416.8	8413.5
Fear	8533.5	8532.4	8533.5	8532.4	8533.5
Susceptibility to colon cancer	5777.2	5777.5	5777.2	5777.5	5777.2
Benefits of colorectal cancer screening	6440.9	6445.1	6440.9	6445.1	6440.9
Barriers to Stool Test	8012.8	8032.7	8012.8	8032.7	8012.8
Barriers to colonoscopy	9499.3	9512.5	9499.3	9512.5	9499.3
Self-efficacy for Stool Test	7528.9	7530.5	7528.9	7530.5	7528.9
Self-efficacy for colonoscopy	8660.3	8659.6	8660.3	8659.6	8660.3
Knowledge for colonoscopy	5136.3	5135.0	5136.3	5135.0	5136.3

Adjusting for the baseline measure of the outcome, and for demographic covariates, we analyzed each knowledge and belief response variable using a mixed linear model. During analysis we tested the interaction term between time and treatment group which resulted in non-significance at alpha of 0.01 (interaction terms were tested at a stricter alpha level due to many interaction terms). Therefore, interaction terms were dropped from the model. The adjusted means of the nine beliefs of CRC screening are shown in Table 3.

Table 3: Adjusted Means

	Overall p-value	Web	Phone	Web + Phone	Usual Care
Fatalism	0.1000	18.2513*	19.1398	18.5163	19.2570
Fear	0.0769	23.4565*	23.2459	22.6796	23.9108
Susceptibility to colon cancer	0.0514	7.2950	7.2191	7.0072**	7.4808
Benefits of colorectal cancer screening	0.1991	19.4375*	19.3333	19.2611	18.9583
Barriers to Stool Test	0.0581	19.0339	18.7279**	18.9704	19.7185
Barriers to colonoscopy	0.0064	31.9033**	32.3096**	32.4296*	34.0590
Self-efficacy for Stool Test	0.0362	29.7059	29.9566*	29.9677*	29.1488
Self-efficacy for colonoscopy	0.6878	38.6055	38.4717	38.3762	38.0260
Knowledge for colonoscopy	<.0001	6.1165***	5.9484**	6.2272***	5.5069

* p<.05, ** p<.01, *** p<.001; p-value indicates the comparison of each intervention to the Usual Care group, from the mixed linear model, adjusted for the baseline measure of the knowledge or belief response variable and adjusted for other baseline covariates in the model.

After adjusting for baseline covariates, at least one of the interventions was shown to be efficacious (compared to usual care) at improving all beliefs except for self-efficacy for colonoscopy (Table 3). Knowledge and perceived barriers demonstrated improvement for all interventions compared to usual care. Perceived benefits of CRC screening, fear, and fatalism showed improvement for the web only group. Barriers for stool test was improved for phone intervention compared to usual care. Susceptibility demonstrated improvement for the Web + Phone group. Self-efficacy for stool test was improved for both phone intervention and Web + Phone intervention. Self-efficacy for obtaining colonoscopy was not statistically significantly improved for any of the interventions compared to usual care.

Chapter 4

DISCUSSION

Five of the nine beliefs were improved by the web only intervention; three of the remaining were improved by the phone only and/or Web + Phone intervention. Since the web-based approach was the most effective overall, there is a strong possibility to decrease cost and increase CRC screening using this web-based approach.

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CURRICULM VITAE

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EDUCATION

- Master of Science in Biostatistics, Indiana University, Indianapolis, IN, 2018
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