A Randomized Trial to Compare a Tailored Web-Based Intervention and Tailored Phone Counseling to Usual Care for Increasing Colorectal Cancer Screening

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Abstract

Background: Colorectal cancer mortality could be decreased with risk-appropriate cancer screening. We examined the efficacy of three tailored interventions compared to Usual Care for increasing screening adherence.

Methods: Women (n=1196) ages 51 to 74, from primary care networks and non-adherent to colorectal cancer guidelines were randomized to: 1) Usual Care, 2) tailored Web intervention, 3) tailored Phone intervention, or 4) tailored Web + Phone intervention. Average-risk women could select either stool test or colonoscopy, while women considered at higher than average risk received an intervention that supported colonoscopy. Outcome data were collected at 6 months by self-report followed by medical record confirmation (attrition of 23%). Stage-of-change for

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colorectal cancer screening (Precontemplation or Contemplation) was assessed at baseline and 6 months.

Results: The Phone (41.7%, $p<.0001$) and combined Web+Phone (35.8%, $p<.001$) interventions significantly increased colorectal cancer screening by stool test compared to Usual Care (11.1%) with odds ratios ranging from 5.4 to 6.8 in models adjusted for covariates. Colonoscopy completion did not differ between groups, except that Phone significantly increased colonoscopy completion compared to usual care for participants in the highest tertile of self-reported fear of cancer.

Conclusion: A tailored Phone with or without a Web component significantly increased colorectal cancer screening compared to Usual Care, primarily through stool testing, and phone significantly increased colonoscopy compared to usual care but only among those with the highest levels of baseline fear.

Impact: This study supports tailored phone counseling with or without a web program for increasing colorectal cancer screening in average risk women.

Keywords

Colon cancer screening; interventions; tailoring; stool test; colonoscopy

Introduction

Despite evidence that breast and colorectal cancer screening can significantly reduce mortality, screening rates fall below the standards set by the Healthy People 2020 initiative (1–3). We report colorectal cancer screening outcomes from a randomized controlled intervention trial supported by the National Cancer Institute and developed to increase colorectal cancer screening using tailored Web and Phone-based interventions. All women were nonadherent to colorectal cancer screening at baseline.

Randomized clinical studies show behavioral interventions, including mailed invitations, telephone counseling, navigation, and a combination of patient navigation and telephone support, significantly increase colorectal cancer screening compared to usual Care (4–7). 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 (8–10). When comparing tailored messages to non-tailored approaches or to motivational interviewing, some research has found tailored messages significantly improve cancer-screening behaviors (11–19). Furthermore, studies found that that allowing average risk individuals to select either stool test or colonoscopy resulted in increased screening (20, 21).

Although tailored interventions are efficacious, most studies have not tailored on a comprehensive set of variables that include baseline stage of change, demographics, and belief variables. (22, 23). With rapid advances in technology, our ability to develop phone or web-based messages tailored to a larger set of variables is possible. Additionally, although prior studies had utilized telephone counseling, at the time the present study was designed, few tailored web-based interventions had been tested, and most phone counseling

interventions did not include tailored messaging. If a web-based approach were efficacious, it could potentially decrease cost and increase dissemination for cancer screening interventions. Finally, it was hypothesized that the additive effect of web plus phone had the potential to increase screening beyond either individual intervention.

Thus, this trial used a full 2×2 factorial design to assess tailored messaging delivered by Web, Phone or both Web+Phone compared to Usual Care to increase completion of colorectal cancer screening. A secondary outcome was stage-of-change for colorectal cancer screening (intention to screen). Covariates included demographics, comorbidities, and baseline colorectal cancer knowledge, beliefs, and stage-of-change for colorectal cancer screening. Specific research questions were:

1. Are there differences between randomized groups and usual care in adherence and stage-of-change for colorectal cancer screening defined as: a) stool test, b) colonoscopy, c) either screening test (stool test or colonoscopy), d) risk-appropriate screening.

Methods

Study design:

A prospective, randomized factorial design compared the impact of three tailored interventions to Usual Care on colorectal cancer screening adherence and stage-of-change to complete colorectal cancer 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. The sample size (at least 200 in each randomized arm) was calculated to yield a power of 80% to detect a 15% difference between each intervention group and Usual Care on the primary outcome of 6 month best-estimate for any CRC screening (e.g., 200 per arm yields 86% power for 35% vs 20%; or 92% power for 50% vs 35%; see Table 2 footnote for the actual sample size, which was slightly greater than 200 per arm. The study was approved by the Institutional Review Board at Indiana University and community sites. This study is registered with the clinical trials identifier NCT03279198 https://clinicaltrials.gov/show/NCT03279198.

Women were interviewed at baseline and 6 months post-intervention. Medical records were obtained at 6 months post-intervention to verify screening and obtain a six month outcome variable, if women dropped prior to 6 month data collection. Women assigned to the Web-based intervention group completed an interactive computer program that provided tailored messages based on their feedback to tailoring questions quieried throughout the program. Women assigned to the Phone intervention received messages from a trained interventionist and tailored to real time feedback-with similar to the Web program. Women assigned to the combination of Web and Phone were first directed to complete of the Web program followed within four weeks by a Phone counseling intervention. If women had not completed the Web program within four weeks of being randomized, research assistants called to schedule the

Phone counseling but emphasized completion of the Web program prior to their Phone counseling appointment.

Eligibility and recruitment:

Women were eligible if they were ages 50 to 75, nonadherent to colorectal cancer screening guidelines, and had access to the internet. To be considered nonadherent, participants had to confirm they had not completed: 1) a fecal stool test in the last 15 months; 2) a sigmoidoscopy in the last 5 years; or 3) a colonoscopy in the last 10 years. Exclusion criteria included: 1) having a personal history of colorectal cancer, colorectal polyps, or inflammatory bowel disease, and 2) having any medical conditions that would prohibit colorectal cancer screening. Although all women were non adherent to colorectal cancer screening, approximately half of the women accrued were currently adherent to breast cancer screening and half non adherent to breast cancer screening. Adherence to breast cancer screening status was used as a covariate.

A list of women ages 50 to 75 with no medical record of guideline-based screening for colorectal cancer or exclusionary criteria in two community-based family health care systems was forwarded to Indiana University's Survey Center whose staff completed all accrual and data collection calls. Prior to calling women, introductory letters were mailed explaining the study and offering an opt-out opportunity through returning a postage-paid postcard or calling a toll-free number. If women did not opt out after two weeks, a call was placed to confirm eligibility and explain details of the study. After confirming eligibility, women were asked if they would participate and verbal consent was obtained for the baseline interview which was completed during the initial conversation. Women were also allowed the opportunity to complete the baseline survey via web. After verbal or web consent, participants were mailed a Health Insurance Portability and Accountability Act (HIPAA) authorization form for release of medical record data and a written informed consent which was mailed back with a postage paid envelop. Data were collected at three times-baseline, two weeks after intervention (process data) and six months after intervention. Participants received a $20.00 gift certificate at each data collection time point.

Outcomes of interest:

Outcomes were completion of colorectal cancer screening by stool test, colonoscopy, either screening test, 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 (24). Therefore, we examined whether women had completed the appropriate test based on their CRC risk (family history). 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 positive 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.

Although kappa coefficients showed adequate agreement (.76 for stool test and .85 for colonoscopy) the best estimate dataset served to decrease potential bias due to missing data in either interview or medical record information.

Measures:

Demographic information, family history, and cancer screening history were assessed using standard questions. Belief scales of perceived risk of colorectal cancer, perceived benefits and barriers to colorectal cancer screening, self-efficacy, fatalism, and fear were measured by scales found to be valid and reliable in past research (25–27). Intention to screen for colorectal cancer and actual screening were assessed by questions successfully used in past research (28).

Interventions

Web only Intervention: A tailored health behavior change intervention was guided by the Health Belief Model, the Transtheoretical Model, and the Likelihood Persuasion Behavioral Theory (29–32). Tailoring focused on key demographic variables (e.g., age, race) and belief variables (mediators) that were theoretically linked to screening behavior in addition to preferred colorectal cancer screening test (33–35). An algorithm embedded in the program directed women at higher than average risk to an intervention that encouraged colonoscopy while women at average risk were allowed to 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 colorectal cancer screening. Messages were developed and refined from previous research using similar tailoring (22). For example, if a woman did not perceive a personal risk for colorectal cancer or benefits of screening, messages were delivered to reinforce the fact that colorectal cancer 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 was delivered suggesting ways to overcome the barrier.

The Web program included graphs, text, videos and animation to reinforce verbal messaging. Further information about development of the tailored program is provided in Supplemental Data Table 1.

Phone only Intervention: A computer program was used to structure the content and flow of the telephone counseling session. The trained interventionists queried women throughout the program to tailor 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. Telephone interventionists were trained during an intensive 2-day session with an opportunity for role playing. All telephone interventions were audio recorded with the

consent of the participant. For people at average risk, the interventionist ask 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.

Treatment fidelity was enhanced by: 1) extensive training of interventionists that included practice and return demonstration of skills; 2) implementation of a process evaluation for all participants to evaluate their receipt of, and satisfaction with, the interventions; and 3) monitoring of a random selection of 101 (17%) recorded telephone interventions with performance feedback as needed (36). Evaluators used a checklist to evaluate each call which included ratings of the degree of completeness and quality of the information delivered by the interventionist.

Web + Phone Intervention: Women randomized to the combined Web and Phone intervention completed the Web program followed within four weeks by Phone counseling. The time for the phone intervention in this arm did not differ significantly from the time used in the phone intervention alone (19 minutes).

Usual Care: Women randomized to Usual Care 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.

Study Endpoints and Analytical Strategy: The primary study endpoint for analyses was colorectal cancer screening test completion at six months post-intervention. Of the 1,196 women who completed baseline interviews, 921 had screening data from either six-month self-report, medical record, or both and were included in analyses. An intent to treat *analyses* (i.e., all participants are analyzed according to randomized group, regardless of adherence to intervention) was completed. However, although we attempted an intent to treat *design* (collect all data on consented participants even if they dropped out before follow up interview), we were not able to obtain outcome data (medical record or self-report) on all participants (36,37).

Four colorectal cancer screening outcomes were created based on best-estimate data from medical record or self-report. Additionally, we modeled stage-of-change for screening with self-report data. (Table 2, Model 2). Women were considered to be in Precontemplation if they did not intend to have colorectal cancer screening in the next six months and in Contemplation if they intended to have colorectal screening in the next six months. Action was defined as being adherent to colorectal cancer screening guidelines and this stage could apply only to women who were adherent at six months. Thus, after intervention, women could move from: 1) Precontemplation to Contemplation; 2) Contemplation to Action (1 step forward); or 3) Precontemplation to Action (2 steps forward).

Multinomial logistic regression models were used to model 6-month stage-of-change by simultaneously estimating odds ratios for women in Action or Contemplation at six months while adjusting for the stage at baseline (either Precontemplation of Contemplation). In binary and multinomial logistic regression models, randomized group assignment and

baseline covariates were entered as the independent variables. Covariates entered were either theoretically justified or differed between randomized groups at the 0.10 alpha level (see covariates listed in Table 2 footnote). Wald chi-square tests, adjusted odds ratios, and 95% confidence intervals were reported. Interactions between the intervention and baseline covariates were tested for potential moderating effects, using a conservative alpha of 0.01.

Results

A total of 1,716 woman were eligible for the study. Of these, 520 refused, resulting in a participation rate of 70%. Of the 1,196 women enrolled, 921 had 6-month follow up data (See Figure 1). Demographic characteristics of the women did not differ by group. (Table 1). The mean age was 58.9 (SD=6.2). A total of 24.3% of women reported a high school education or less, 42% reported one or more years post high school and 30.2% reported a 4-year college degree or higher. The predominant race was Caucasian (86.3%), while 10.4% of participants were African-American. A total of 60% were married or living with a partner. Income was distributed as $30,000 or less (31.2 %), $30,001 to $75,000 (41.2%), $75,001 or above (27.6%).

Univariate analyses of colorectal cancer screening outcomes is illustrated in Figure 2. Percentages of women adherent at six months to **any colorectal cancer screening test** (Web=22.7%, Phone=52.5%, Web+Phone=44.4%, Usual Care=24.6%) were very similar to the percentages adherent to **risk-appropriate colorectal cancer screening** (Web=21.8%, Phone=52.3%, Web+Phone=43.7%, Usual Care=24.6%). Colonoscopy rates did not differ by group.

Logistic regression was used to compare interventions groups to Usual Care on each 6-month screening outcome while controlling for important covariates (See Table 2 and footnote). Model 1 in Table 2 identifies the p-values and adjusted odds ratios for colorectal cancer screening at 6 months by intervention group. Because none of the theoretically identified covariates had significant odds ratios after adjusting for each other, we display only the group differences in tables. Screening adherence at six months for **any colorectal cancer screening test or for risk-appropriate colorectal cancer screening** was significantly higher for women in the Phone and Phone+Web intervention groups (p<0.0001) compared to the Usual Care. Completion of a **stool test** was similar across groups (Web=11.9%, Phone=41.7%. Web + Phone=35.8%, and Usual Care=11/1%). Adherence for **colonoscopy** was low (Web, 11.8%, Phone, 17.2%, Web+Phone 15.0% and Usual Care 15.3%)-with no significant differences across groups.

The four randomized groups were compared on stage-of-change to screen. In Model 2 (Table 2), the odds of being in Contemplation or Action (versus pre-contemplation) at 6 months are reported, adjusted for baseline stage and covariates. Demographic and experiential variables entered into the equation were not significant. Table 2 provides data to interpret efficacy to move or retain participants to Contemplation or to move participants to Action, adjusted for baseline stage. All three intervention arms (including Web only) were significantly better than Usual Care in increasing the odds for being in Contemplation vs Precontemplation at 6 months for **any colorectal cancer screening test** (Web p<0.0140,

Phone $p<0.0057$, Web+Phone $p<0.0032$), for **risk-appropriate** colorectal cancer screening (Web $p=0.0179$, Phone $p<0.0270$, Web+Phone $p<0.0053$), and for **stool test** (Web $p<0.0100$, Phone $p<0.0281$, Web +Phone $p=0.0017$). Compared to Usual Care, none of the interventions had a significant effect on 6-month stage-of-change for **colonoscopy.**

When considering efficacy to move participants to Action from Precontemplation at 6 months for **any colorectal cancer screening test** the Web was marginally significant (p<0.0537), while the Phone ($p<0.00001$), Web+Phone ($p<0.0001$), were very significant compared to Usual Care. For **risk-appropriate colorectal cancer screening,** Phone ($p<0.00001$) and Web+Phone ($p<0.0001$) interventions were significantly different than Usual Care in moving women to from Precontemplation to Action. For **stool tests**, the Phone ($p<0.0001$) and Web+Phone ($p<0.0001$) interventions were significantly better than Usual Care for moving women from Precontemplation to Action. Intervention arms were not different from Usual Care in completion of **colonoscopy.**

Interaction tests revealed only one significant interaction at 0.01 alpha between intervention effects and baseline covariates (p = 0.0008). Specifically, post-hoc simple effects showed that among participants in the highest tertile of baseline fear scores (n = 253), Phone was significantly more effective than usual care at moving participants to obtain a colonoscopy (odds ratio = 16.39 [2.84, 94.79], p = .002).

Discussion

Results demonstrate the significant impact of Phone counseling to promote colorectal screening. Importantly, the interventions that included Phone included the proactive offer of a mailed stool kit. It is probable that a stool test mailed to their home was the major factor producing the large effect sizes found for Phone and Phone+Web in this study, consistent with other researchers who found that mailing stool test kits increased colorectal cancer screening (7). In particular, Singal found that mailing stool test kits to primary care patients resulted in participation rates of close to 59% (38).

Another factor that may have increased the effects found in this study was allowing average risk women (95%) to select preferred tests. Myers studied 764 African Americans ages 50 to 75 and found that in an intervention, which included a navigation component, persons who expressed a preference for stool testing were much more likely to obtain a stool test than a colonoscopy (41.1% vs. 7.1%) (39). The comparison group, with no personal contact, showed a much smaller advantage for stool testing among persons who expressed a preference (12.1% vs. 7.6%), even though a stool kit had been mailed to them. The personal contact with an interventionist may be an important factor (39).

We cannot conclude that tailoring played a role in the large effect found with our Phone intervention groups. Without a non-tailored phone intervention arm, we do not know if the tailoring used for phone messaging increased stool testing beyond what a non-tailored phone call and mailing stool kits would have accomplished. The fact that the tailored Web-based program did not increase screening and the tailored Phone intervention with mailed stool kits did, suggests that tailoring did not add to the effectiveness of the Phone intervention,

although, it is possible that the interaction of tailoring and personal contact by phone added to the effect size we found. Additionally, we have no way of knowing whether mailing a stool kit without a tailored web or phone intervention would have been more effective than usual care.

The tailored Web-based intervention did not increase stool testing compared to Usual Care, a finding supported by other studies using a web-based approach. In a similar attempt to use a tailored interactive computer intervention to promote colorectal cancer screening, Vernon did not find a significant difference in randomized groups comparing a tailored interactive computer program, an informational web program or a survey only group for improving colorectal cancer screening (40). Our decision to use a Web-based approach as one media for delivery reflected the growing penetration of households that now have high speed internet- approximately 75% (46) and the hope that this less expensive intervention could increase screening. The combination of Web plus Phone, although significantly different from Usual Care, produced slightly lower effect sizes than the Phone alone, suggesting that in the presence of Phone outreach, a web-based intervention did not add to the effect.

Rates of colonoscopy screening were not significantly different for any intervention group compared to Usual Care, except when considering the moderating effect of fear. In retrospect, this outcome is understandable. Women at average risk were allowed to select a preferred test and if screening by stool test was the preferred modality, colonoscopy was not promoted, and the intervention focused on stool testing. Furthermore, 95% of women in our sample were at average risk and of those assigned to intervention groups, (Usual Care didn't select preferred test) 63% stated preference for stool test, 37% stated preference for colonoscopy, and 1% did not state preference. Given the overwhelming preference for stool testing, it is probable that the intervention forestalled women from thinking about colonoscopy. However, research suggests that for women at higher than average risk, phone interventions have significantly increased colonoscopy compared to usual care (41–43). Kinney (2014) tested a telehealth intervention with relatives of colorectal patients using tailored content via phone outreach compared to a mailed educational brochure and found the telehealth intervention resulted in 35.4% of those in the telehealth vs only 15.7% in the mailed brochure completed colonoscopy (43). Additionally, in a sample of high-risk individuals with a family history of colorectal neoplasia, a tailored nurse led intervention resulted in a significant uptake of colonoscopy compared to control (p=.0027) (44).

Demographic and belief variables were tested for moderation and the only significant (alpha 0.10) interaction was between the phone only group and higher levels of fear. Among those with the highest levels of baseline fear of cancer, the Phone intervention group had significantly higher rates of obtaining colonoscopy that Usual Care. This suggests a future opportunity to move high-risk persons to obtain colonoscopy if they report higher levels of fear of cancer.

Although stages of change have been used in a range of behavioral interventions, its use has been limited for studies assessing colorectal cancer screening. We tested the ability of any intervention group compared to Usual Care to advance stage movement for colon cancer screening. All three interventions, including the Web, were successful in promoting forward

stage movement from Precontemplation to Contemplation. Additionally, the Web-based intervention, like interventions with phone counseling was marginally significant in moving women in Precontemplation at baseline to Action. A research study that also used stage movement in analyses found an intervention effect for forward stage movement, although no overall increase in actual screening was found (40). Our Web-based intervention included compelling stories from other women about the necessity to screen, an animation of how cancer develops and a visual description of screening tests; perhaps these elements were most important for women who were not considering screening at baseline, allowing the Web-based intervention to increase screening for women at the 6-month follow-up.

Limitations

As with all studies, results of this RCT should be interpreted within the context of the study's limitations. Women comprised a volunteer sample and included only 70% of those invited. Additionally, women were primarily Caucasian and patients of family practice clinics, already engaged with the medical care system. Results could differ for persons without a health care home or for women of color or Hispanic origin. Furthermore, we were not able to follow women to determine intervention effectiveness for having subsequent annual stool testing. We implemented an intent-to treat design, however, because outcome data were not available on all consented participants, the number analyzed was smaller than the number consented. Finally, additional research is needed to determine the most effective intervention that will support colonoscopy, especially for those women at higher than average risk who require a colonoscopy.

Conclusion

The tailored Phone interventions with or without a Web-based program, significantly increased screening for all participants by stool tests, with the large effect sizes probably due to outreach by Phone and proactive mailing of preferred test (stool kit). The tailored web-based intervention increased screening only in the subgroup of women in Precontemplation at baseline although this finding was only marginally significant. The interventions tested in this study did not increase screening by colonoscopy-with the exception of those with high fear at baseline- possibly because 95% of women were at average risk and were allowed to select their preferred screening test which was most often stool test instead of colonoscopy.

Acknowledgements

Abbreviation list:

HIPAA	Health Insurance Portability and Accountability Act
OR	odds ratio
RCT	randomized controlled trial

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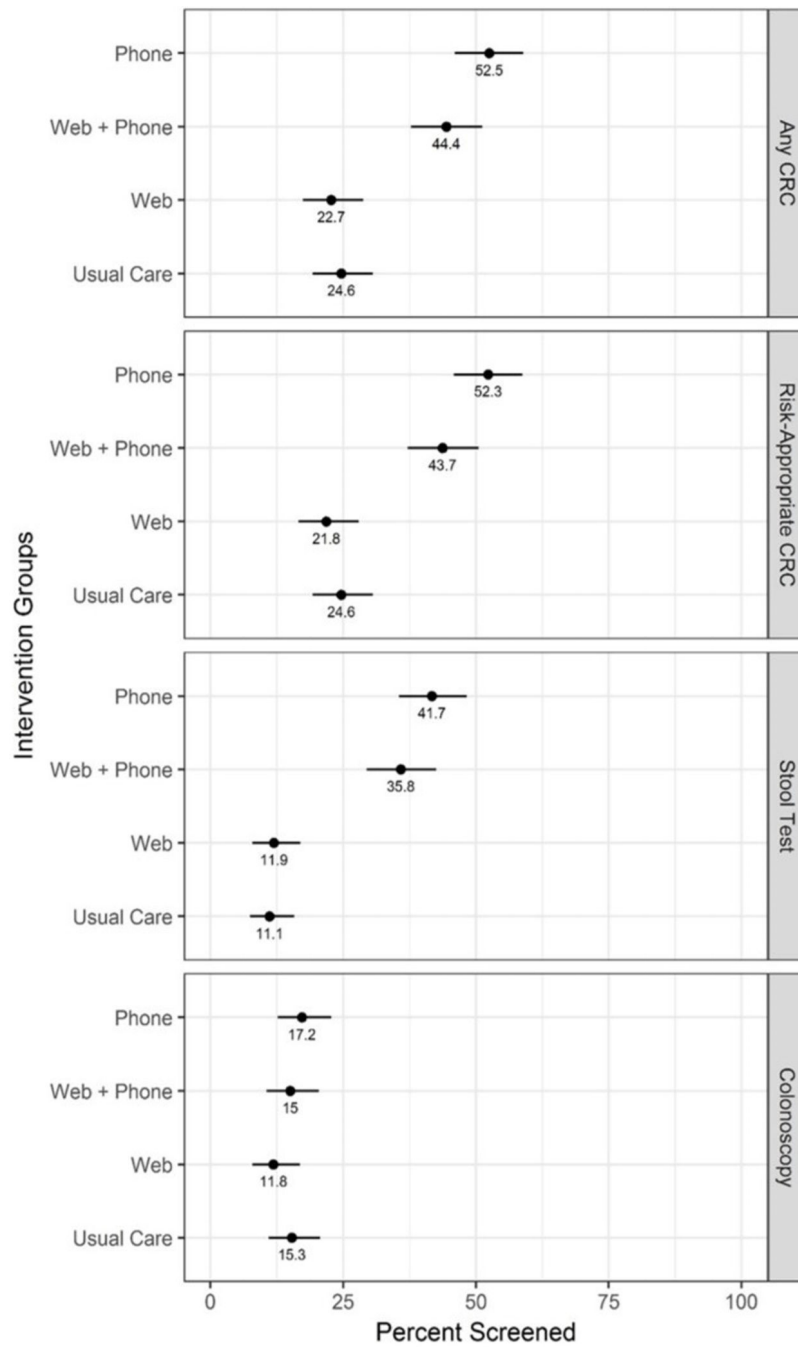
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Enrollment

Assessed for eligibility
(n=8355)

Excluded (n=7159)
- Opted out (n=801)
- Contacted, but opted out prior to determining eligibility (n=2274)
- Did not meet inclusion criteria (n=3564)
- Declined to participate (n=431)
- Consented, but no further contact (n=89)

Randomized (n=1196)

Allocation

Allocated to **Usual Care (UC)** (n=305)

Allocated to **Web Intervention (Web)** (n=303)
Received intervention (n=175)
Did not receive intervention (n=128)
Lost to FU prior to intervention (n=81)
Completed T2 assessment but not intervention (n=47)

Allocated to **Phone** (n=296)
Received intervention (n=256)
Did not receive intervention (n=40)
Lost to FU prior to intervention (n= 23)
Completed T2 assessment but not intervention (n=17)

Allocated to **Web + Phone** (n=292)
Received intervention (n=241)
Did not receive intervention (n=51)
Lost to FU prior to intervention (n= 44)
Completed T2 assessment but not intervention (n=7)

Follow Up

UC Lost to follow-up, (n=69) 23%
No self-report (SR) or medical records (MR) data on 6 month outcome

Web Lost to follow-up (n=83) 27%
No self-report (SR) or medical records (MR) data on 6 month outcome

Phone Lost to follow-up (n=54) 18%
No self-report (SR) or medical records (MR) data on 6 month outcome

Web+Phone Lost to follow-up (n=69) 24%
No self-report (SR) or medical records (MR) data on 6 month outcome

Analysis

UC analyzed (n=236)
Self-report (SR)=204
Medical records (MR)=175
SR and/or MR=236

Web analyzed (n=220)
Self-report (SR)=174
Medical records (MR)=168
SR and/or MR=220

Phone analyzed (n=242)
Self-report (SR)=207
Medical records (MR)=195
SR and/or MR=242

Web+Phone analyzed (n=223)
Self-report (SR)=165
Medical records (MR)=195
SR and/or MR=223

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

Figure 2:
Comparisons of 6 Month Colorectal Cancer Screening outcomes between Randomized Groups Using Best-Estimate Data

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**

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
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

Note. For continuous variables and ordinal income, the two-sided independent-groups t-test was used unless parametric assumptions were violated in which case the two-sided Kruskal-Wallis test was used. For categorical variables, the chi-square test was used. HCP = health care provider. COLORECTAL CANCER = colorectal cancer

Table 2.

Logistic Regression (LR) Models of 6 Month (T3) Colorectal Cancer Outcomes

Outcomes & Randomized Groups	Best-Estimate Data (Medical Record and Self-Report)		Self-Report Data (Stage)			
	Model 1 (Binary LR Model) T3 Screen (yes/no)		Model 2 (Generalized LR Model; reference category = T3 Precontemplation)			
			T3 Contemplation		T3 Action	
	Adjusted OR	*p*-value	Adjusted OR	*p*-value	Adjusted OR	*p*-value
Any Colorectal Cancer screening test						
Web only	1.01 (0.63, 1.62)	.9626	1.97 (1.14, 3.40)	.0152	1.81 (0.99, 3.30)	.0537
Phone only	4.00 (2.60, 6.16)	<.0001	2.37 (1.28, 4.39)	.0058	7.94 (4.33, 14.56)	<.0001
Web + Phone	2.69 (1.73, 4.18)	<.0001	2.52 (1.33, 4.77)	.0045	6.68 (3.56, 12.54)	<.0001
Risk-appropriate colorectal cancer test						
Web only	0.94 (0.59, 1.51)	.7982	1.92 (1.11, 3.32)	.0195	1.62 (0.89, 2.96)	.1163
Phone only	4.00 (2.60, 6.17)	<.0001	1.99 (1.08, 3.67)	.0277	7.07 (3.89, 12.85)	<.0001
Web + Phone	2.59 (1.67, 4.03)	<.0001	2.37 (1.26, 4.48)	.0076	6.08 (3.26, 11.34)	<.0001
Stool test						
Web only	1.20 (0.64, 2.24)	.5772	2.07 (1.17, 3.67)	.0126	1.78 (0.86, 3.68)	.1208
Phone only	6.80 (3.98, 11.60)	<.0001	1.93 (1.04, 3.57)	.0364	9.81 (5.21, 18.48)	<.0001
Web + Phone	5.37 (3.11, 9.29)	<.0001	2.86 (1.50, 5.45)	.0014	12.14 (6.26, 23.57)	<.0001
Colonoscopy						
Web only	0.70 (0.37, 1.33)	.2794	1.02 (0.57, 1.80)	.9516	0.96 (0.46, 1.97)	.9005
Phone only	1.39 (0.77, 2.52)	.2717	0.64 (0.35, 1.14)	.1285	1.38 (0.70, 2.70)	.3534
Web + Phone	0.88 (0.48, 1.61)	.6750	0.83 (0.46, 1.49)	.5275	0.84 (0.41, 1.72)	.6274

*
Models adjusted for baseline characteristics including age, race (African American *vs* Other), education, income, marital status, BMI, whether depression limits patient's activities (yes/no), family history of 1 or more blood relatives with colon cancer (yes/no), perceived risk, doctor recommendation (yes/no), number of past-year primary care visits excluding eye care and dentistry (>=3), number of self-reported health problems, baseline adherence to mammography screening (yes/no), baseline stage of change for colorectal cancer screening, knowledge, susceptibility, benefits, fear, fatalism, self-efficacy, and barriers. Self-efficacy and barriers specific for colonoscopy or stool test were used in colonoscopy and stool test models, respectively. Sample sizes for Models 1 and 2, respectively, were: any colorectal cancer (843, 683), risk appropriate colorectal cancer (842, 681), stool test (836, 642), and colonoscopy (835, 643).