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 with usual care for increasing screening adherence.

Methods: Women (n = 1,196) ages 51 to 74, from primary care networks and nonadherent 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, whereas 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 colorectal cancer screening (precontemplation or contemplation) was assessed at baseline and 6 months.

Results: The phone (41.7%, P < 0.0001) and combined Web + phone (35.8%, P < 0.001) interventions significantly increased colorectal cancer screening by stool test compared with usual care (11.1%), with ORs 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 with usual care for participants in the highest tertile of self-reported fear of cancer.

Conclusions: A tailored phone with or without a Web component significantly increased colorectal cancer screening compared with usual care, primarily through stool testing, and phone significantly increased colonoscopy compared with 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. Cancer Epidemiol Biomarkers Prev; 27(12); 1433–41. ©2018 AACR.

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 (NCI) 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 with 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 for various health behaviors (8–10). When comparing tailored messages to nontailored approaches or to motivational interviewing, some research has found tailored messages significantly improve cancer screening behaviors (11–19). Furthermore, studies found 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...
With rapid advances in technology, our ability to develop phone or Web-based messages tailored to a larger set of variables is possible. In addition, 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 was 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 with 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: Are there differences between randomized groups and usual care in adherence and stage of change for colorectal cancer screening defined as (i) stool test, (ii) colonoscopy, (iii) either screening test (stool test or colonoscopy), and (iv) risk-appropriate screening?

**Materials and Methods**

**Study design**

A prospective, randomized factorial design compared the impact of three tailored interventions with usual care on colorectal cancer screening adherence and stage of change to complete colorectal cancer screening. A total of 1,196 women 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 CONSolidated Standards Of Reporting Trials (CONSORT) diagram is illustrated in Fig. 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 colorectal cancer screening (e.g., 200 per arm yields 86% power for 35% vs. 20% or 92% power for 50% vs. 35%; see Table 1 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 at https://clinicaltrials.gov/show/NCT03279198.

Women were interviewed at baseline and 6 months after intervention. Medical records were obtained at 6 months after intervention to verify screening and obtain a 6-month outcome variable, if women dropped-out 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 queried throughout the program. Women assigned to the phone intervention received messages from a trained interventionist that were tailored in real time based upon participant feedback (similar to the Web program). Women assigned to the combination of Web and phone were first directed to complete the Web program followed within 4 weeks by a phone counseling intervention. If women had not completed the Web program within 4 weeks of being randomized,
Tailored Interventions to Increase Colorectal Cancer Screening

Table 1. Logistic regression models of 6-month (T3) colorectal cancer outcomes

<table>
<thead>
<tr>
<th>Outcomes and randomized groups</th>
<th>Best-estimate data (medical record and self-report)</th>
<th>Self-report data (stage)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model 1 (binary LR model; reference category = T3 precontemplation)</td>
<td>Model 2 (generalized LR model; reference category = T3 precontemplation)</td>
</tr>
<tr>
<td></td>
<td>T3 screen (yes/no)</td>
<td>T3 contemplation</td>
</tr>
<tr>
<td>Adjusted OR</td>
<td>P value</td>
<td>Adjusted OR</td>
</tr>
<tr>
<td>Any colorectal cancer screening test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Web only</td>
<td>1.01 (0.63-1.62)</td>
<td>0.9626</td>
</tr>
<tr>
<td>Phone only</td>
<td>4.00 (2.60-6.16)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Web + phone</td>
<td>2.69 (1.73-4.18)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Risk-appropriate colorectal cancer test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Web only</td>
<td>0.94 (0.59-1.51)</td>
<td>0.7982</td>
</tr>
<tr>
<td>Phone only</td>
<td>4.00 (2.60-6.17)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Web + phone</td>
<td>2.59 (1.67-4.03)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stool test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Web only</td>
<td>1.20 (0.64-2.24)</td>
<td>0.5772</td>
</tr>
<tr>
<td>Phone only</td>
<td>6.80 (3.98-11.60)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Web + phone</td>
<td>5.37 (3.11-9.29)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Web only</td>
<td>0.70 (0.37-1.35)</td>
<td>0.2794</td>
</tr>
<tr>
<td>Phone only</td>
<td>1.39 (0.77-2.52)</td>
<td>0.2777</td>
</tr>
<tr>
<td>Web + Phone</td>
<td>0.88 (0.48-1.61)</td>
<td>0.6750</td>
</tr>
</tbody>
</table>

NOTE: Models adjusted for baseline characteristics including age, race (African American vs. other), education, income, marital status, body mass index, 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). Bold indicates P value < 0.05. Abbreviation: LR, logistic regression model.

Participants 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 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 nonadherent to colorectal cancer screening, approximately half of the women accrued were currently adherent to breast cancer screening and half nonadherent 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 2 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 authorization form for release of medical record data and a written informed consent that was mailed back with a postage-paid envelope. Data were collected at three times—baseline, 2 weeks after intervention (process data), and 6 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 colorectal cancer 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 colorectal cancer 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 colorectal cancer risk (based upon 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 dataset 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 dataset allowed us to include women who did not have 6-month self-report but had medical record data or conversely allowed use of self-report data, if medical record data were not available. Although kappa coefficients showed adequate agreement (0.76 for stool test and 0.85 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 assessed (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, whereas 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 that 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 believe a personal risk for colorectal cancer or barriers 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 Supplementary Table S1.

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 interventionists ask about their preferred tests, and if a woman stated stool test, it was mailed to their home. If the woman was 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 4 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 6 months after intervention. Of the 1,196 women who completed baseline interviews, 921 had screening data from either 6-month self-report, medical record, or both and were included in analyses. An intent-to-treat analysis (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. In addition, we modeled stage of change for screening with self-report data (Table 1, model 2). Women were considered to be in precontemplation if they did not intend to have colorectal cancer screening in the next 6 months and in contemplation if they intended to have colorectal screening in the next 6 months. Action was defined as being adherent to colorectal cancer screening guidelines, and this stage could apply only to women who were adherent at 6 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 ORs for women in action or contemplation at 6 months while adjusting for the stage at baseline (either precontemplation or 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 1 footnote). Wald $\chi^2$ tests, adjusted ORs, 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 women 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 Fig. 1). Demographic characteristics of the women did not differ by group.
Married or living with a partner 719 (60.4) 182 (60.1) 188 (64.0) 171 (58.8) 178 (58.8) 0.4493
to any colorectal cancer screening test (Web illustrated in Fig. 2. Percentages of women adherent at 6 months (41.2%), or $75,001 or above (27.6%).

Income was distributed as $30,000 or less (31.2%), $30,001 to $75,000 (44.4%), $75,001 or above (24.6%) with no significant differences across groups.

Logistic regression was used to compare interventions groups with usual care on each 6-month screening outcome while controlling for important covariates (see Table 1 and footnote). Model 1 in Table 1 identifies the P values and adjusted ORs for colorectal cancer screening at 6 months by intervention group. Because none of the theoretically identified covariates had significant ORs after adjusting for each other, we display only

Table 2. Baseline characteristics by randomized group

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Total sample</th>
<th>Web (n = 303)</th>
<th>Phone (n = 296)</th>
<th>Web + phone (n = 292)</th>
<th>Usual care (n = 305)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) or mean (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor or HCP ever suggested you do a stool test? n (%) responding yes</td>
<td>458 (38.3)</td>
<td>120 (39.6)</td>
<td>119 (40.2)</td>
<td>108 (37.0)</td>
<td>111 (36.5)</td>
<td>0.7304</td>
</tr>
<tr>
<td>Doctor ever recommended that you have a colonoscopy? n (%) responding yes</td>
<td>785 (65.8)</td>
<td>194 (64.2)</td>
<td>192 (65.1)</td>
<td>201 (68.8)</td>
<td>198 (65.1)</td>
<td>0.6480</td>
</tr>
<tr>
<td>Baseline adherence to breast cancer screening</td>
<td>504 (42.1)</td>
<td>125 (40.6)</td>
<td>128 (43.2)</td>
<td>125 (42.8)</td>
<td>128 (42.0)</td>
<td>0.9185</td>
</tr>
<tr>
<td>Baseline colorectal cancer screening stage, n (%) in contemplation at baseline; (n, % in precontemplation can be calculated as 100 — % shown below)</td>
<td>1,196</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor or HCP ever suggested you do a stool test?</td>
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<td>201 (68.8)</td>
<td>198 (65.1)</td>
<td></td>
<td>0.6480</td>
</tr>
<tr>
<td>Any colorectal cancer screening</td>
<td>785 (65.8)</td>
<td>201 (68.8)</td>
<td>201 (68.8)</td>
<td>198 (65.1)</td>
<td></td>
<td>0.6480</td>
</tr>
<tr>
<td>Risk-appropriate colorectal cancer screening</td>
<td>785 (65.8)</td>
<td>201 (68.8)</td>
<td>201 (68.8)</td>
<td>198 (65.1)</td>
<td></td>
<td>0.6480</td>
</tr>
</tbody>
</table>

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
Perceived age-adjusted risk for colon cancer, n (%) 0.6297
Barrier to colonoscopy 36.1 (8.7) 36.0 (8.8) 36.6 (9.0) 36.3 (8.9) 35.3 (8.0) 0.2744
Barrier to stool test 20.1 (5.0) 19.9 (5.3) 20.4 (5.0) 20.1 (5.1) 19.9 (4.6) 0.5571

Self-efficacy for stool test 28.4 (4.8) 28.4 (4.8) 28.2 (5.3) 28.4 (4.7) 0.5341
Self-efficacy for colonoscopy 36.9 (7.2) 36.7 (7.5) 36.7 (7.5) 36.7 (7.5) 37.3 (6.7) 0.7387

Knowledge of colorectal cancer and colorectal cancer screening 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 y² test was used. Bold indicates P value < 0.05.

Abbreviation: HCP, health care provider.
the group differences in tables. Screening adherence at 6 months for any colorectal cancer screening test or for risk-appropriate colorectal cancer screening or for stool test was significantly higher for women in the phone and phone + Web intervention groups (P < 0.0001) compared with the usual care.

The four randomized groups were compared on stage of change to screen. In model 2 (Table 1), the odds of being in contemplation or action (versus precontemplation) at 6 months are reported, adjusted for baseline stage and covariates. Demographic and experiential variables entered into the equation were not significant. Table 1 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 versus 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 with usual care, none of the interventions had a significant effect on 6-month stage of change for colonoscopy.

Figure 2.
Comparisons of 6-month colorectal cancer (CRC) screening outcomes between randomized groups using best-estimate data.

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), whereas the phone (P < 0.00001) and Web + phone (P < 0.0001) were very significant compared with 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 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 these participants to obtain a colonoscopy [OR, 16.39 (2.84-94.79), P = 0.002].

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 and colleagues 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 and colleagues 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%; ref. 39). The comparison group, with no personal contact, showed a much smaller advantage for usual care moving women from precontemplation to action (7). In particular, Singal and colleagues found that mailing stool test kits to primary care patients resulted in participation rates of close to 59% (38).

We cannot conclude that tailoring played a role in the large effect found with our phone intervention groups. Without a nontailored phone intervention arm, we do not know if the tailoring used for phone messaging increased stool testing beyond what a nontailored 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 suggest 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 we found. In addition, 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 with 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 and colleagues 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 medium for delivery reflected the growing number 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 with 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 did not 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 with usual care (41–43). Kinney and colleagues tested a telehealth intervention with relatives of colorectal patients using tailored content via phone outreach compared with a mailed educational brochure and found the telehealth intervention resulted in 35.4% of those in the telehealth versus only 15.7% in the mailed brochure completed colonoscopy (43). In addition, 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 with control ($P = 0.0027$; ref. 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 with 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. In addition, 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 randomized controlled trial (RCT) should be interpreted within the context of the study’s limitations. Women comprised a volunteer sample and included only 70% of those invited. In addition, 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 consenting participants, and 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.

**Conclusions**

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.

**Disclosure of Potential Conflicts of Interest**

No potential conflicts of interest were disclosed.

**Disclaimer**

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**Authors’ Contributions**

Conception and design: V.L. Champion, W. Rakowski, S.M. Rawl
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Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): V.L. Champion, W. Rakowski, W.G. Gathumba-Mwangi, T.E. Stump, P. Monahan, S.M. Rawl
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V.L. Champion and P. Monahan had full access to all of the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis. V.L. Champion, C.D. Kettler, T.E. Stump, and P. Monahan, all from Indiana University, conducted and are responsible for the data analysis.

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References

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