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ECONOMIC EVALUATION OF WEB VS. TELEPHONE BASED INTERVENTIONS TO SIMULTANEOUSLY INCREASE COLORECTAL AND BREAST CANCER SCREENING AMONG WOMEN

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Abstract

Screening for colorectal and breast cancer is considered cost effective, but limited evidence exist on cost-effectiveness of screening promotion interventions that simultaneously target both cancers. Project COBRA, Increasing Colorectal and Breast Cancer Screening, a randomized controlled trial conducted in the community, examined the cost-effectiveness of an innovative tailored web-based intervention compared to tailored telephone counseling and usual care.

Screening status at 6 months was obtained by participant surveys plus medical record reviews. Cost was prospectively measured from the patient and provider perspectives using time logs and project invoices. Relative efficiency of the interventions was quantified by the incremental cost-effectiveness ratios. Non-parametric bootstrapping and net benefit regression analysis were used to assess statistical uncertainty of the results.

The average cost per participant to implement the Phone counseling, Web-based and Web + Phone counseling interventions were $277, $314 and $337, respectively. Comparing Phone counseling to usual care resulted in an additional cost of $300 (95% confidence interval (CI): $283-$320) per cancer screening test and $421 (95% CI: $400-$441) per additional person screened in the target population. Phone counseling alone was more cost-effective than the Web + Phone intervention. Web-based intervention alone was more costly but less effective than the Phone counseling.

When simultaneously promoting screening for both colorectal and breast cancer the Web-based intervention was less cost-effective compared to Phone and Web + Phone strategies. The results suggest that targeting multiple cancer screening may improve the cost-effectiveness of cancer screening interventions.

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Keywords

colorectal cancer; breast cancer; screening; cost-effectiveness; Web-based; Telephone Counseling

INTRODUCTION

Colon and breast cancers are two of the top three most commonly detected cancers in women, and colorectal cancer is the third leading cause of cancer death. Screening can find colorectal cancer and breast cancer early when treatment is both more effective and cost-effective (1, 2). The American Cancer Society (ACS) (3), the United States Preventive Services Task Force (USPSTF) (https://www.uspreventiveservicestaskforce.org) (4) and National Comprehensive Cancer Network (5) recommend regular interval screening for both breast and colon cancers. In 2015, only 63.1% and 71.6% of women were adherent to colorectal and breast cancer screening guidelines, respectively (6). Healthy People 2020 screening goals were 70.5% for colorectal cancer and 81.1% for breast cancer screening (https://www.healthypeople.gov/2020) (6). There is a need to develop and implement cost-effective interventions to increase adherence to both breast and colon cancer screening to meet the 2020 goals.

By addressing adherence to more than one cancer screening guideline, cancer prevention programs can potentially target their resource allocation to achieve the largest health gains for the available dollars. For example, healthcare programs can promote both colorectal cancer and breast cancer screening for women who are non-adherent to both to increase efficiency, decrease the need for multiple interventions and thereby reduce costs (7).

Screening promotion interventions have applied “tailoring” based on the specific attitudes, knowledge and beliefs of the participants (8, 9) and demonstrated superiority in promoting mammogram adherence (10-12). Effectiveness of tailored colorectal cancer interventions was also demonstrated in several studies (13-20) but not all (21, 22). A systematic review reported that tailored interventions increased breast, cervical or colorectal cancer screening rates by 6%-23.4% (23).

Tailored interventions increase screening by addressing an individual’s specific beliefs, attitudes and barriers to screening, but tailoring adds to the cost of developing and implementing screening interventions. Therefore, it is important to inform decision makers about the cost-effectiveness of tailored interventions and the uncertainties associated with projecting the results of studies to “real world” applications. A few studies have examined the cost-effectiveness of tailored breast and colorectal cancer screening promotions. Estimates of tailored colorectal screening intervention delivery costs range from $2.49-$1,089 (11-19) per participant, which lead to a cost per additional person screened in the target population of $15 to $21,124 (11-17, 19, 20). This wide range of estimates may be due to different study populations, whether recruitment costs were included, and intervention modes (print, telephone or multimedia). For example, tailored breast cancer screening interventions cost $4.14-$52 per person to deliver, and $50.43 to $1,116 per additional person screened (Lairson 2010; Saywell 1999; Saywell 2004). However, only one intervention targeted more than one cancer screening, i.e, cervical and breast cancer

screening (Lynch 2004). Lynch and colleagues reported an incremental cost of $818 in 2000 US dollars to have one additional woman undergo Pap smear and mammography screening with a tailored letter and a phone call. Prior studies have neither evaluated the economics of combining colorectal and breast cancers screening, nor compared Web-based screening interventions to more traditional telephone counseling strategy.

The objective of our study was to estimate the incremental cost-effectiveness of 3 tailored interventions designed to increase colorectal and breast cancer screening among women. This trial compared a usual care/control group to groups that received: 1) Phone counseling, 2) a Web Program, and 3) the Web program + Phone counseling. Results will inform researchers, decision makers, healthcare providers and payers about the cost-effectiveness of alternative intervention designs and resource allocation for colorectal and breast cancer early detection in women 50 and older.

MATERIALS AND METHODS

In 2013-2015, two community-based family healthcare systems that included primary care practices in Indiana agreed to participate in a randomized controlled trial (RCT) (https://clinicaltrials.gov/show/NCT03279198). One healthcare system served underinsured and underserved population regardless of ability to pay. The other one was a for profit large community based system that served mainly insured population. Therefore, the targeted population included women with different socioeconomic status. Women were eligible if they were ages 50 to 75, had access to the internet, and were non-adherent to colorectal cancer and breast cancer screening guidelines. Non-adherence was defined as having had neither: 1) a fecal occult blood test or fecal immunochemical test in the last 15 months; 2) a sigmoidoscopy in the last 5 years; nor 3) a colonoscopy in the last 10 years, and 4) not having had a mammogram in the last 15 months. Women were excluded if they had a personal history of colorectal cancer, colorectal polyps, or inflammatory bowel disease; or had any medical conditions that would prohibit breast or colon cancer screening. A list of women ages 50 to 75 with no medical record of guideline-based screening for colorectal cancer or exclusionary criteria in the two healthcare 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. Supplemental Figure 1 presents the consort diagram of the RCT (24). A total of 4,834 women were assessed for eligibility. Among them, 2,062 were found to be ineligible; 1,316 opted out prior to determining eligibility; 464 opted out; 249 actively refused; and 51 consented but had no further contact. The current analysis includes 692 women who were non-adherent to both colorectal cancer and breast cancer screening. Participants signed a

written consent, and were randomized to one of four groups: (1) Usual Care, (2) Phone counseling, (3) Web-based counseling, or (4) a Web-based + Phone counseling intervention (supplemental Figure 1). All interventions were individually tailored. Participants were surveyed at baseline, 2 weeks, and 6 months. Participants received a $20.00 gift certificate at each data collection time point. Table 1 presents the baseline characteristics by intervention group. The details of the interventions, methods, and screening results of the study described elsewhere (24). Indiana University and community intervention clinics' institutional review boards approved the study. The study was conducted in accordance with U.S. Common Rule.

Interventions

Web-based intervention: The Web-based program utilized a talk show format and combined audio dialogues and survey questions to accommodate women with low literacy. The Web intervention included photographs, video clips, animations, graphics and tailored messages. Tailoring was based on demographic variables (e.g., age, race), health belief variables (e.g., perceived barriers), and objective risk for developing colorectal cancer. The tailored messages were based on the individual's knowledge, perceived and actual risk to breast and colon cancer, as well as benefits, barriers, and self-efficacy to both breast and colon cancer screening. Video clips illustrate the screening procedures of mammography, stool tests and colonoscopy.

Phone counseling: Tailored messages delivered by a trained research associate via phone calls averaged about 20 minutes. The message content was consistent with that provided by the Web-based programming. Research associates were trained over two days with role playing methods. All phone calls were audio recorded and reviewed later for appropriate delivery of content using a fidelity checklist.

Web + Phone intervention: Women receiving the combined intervention first completed the Web program with the phone intervention delivered two to four weeks later.

Usual Care: women in this group received usual care which varied by clinic but could include health education information at the clinic or possible postcard reminders for cancer screenings.

Cost estimation

Cost estimation was conducted from the perspectives of payers and participants. The costs of activities, i.e., program planning, intervention staff training, identification and recruitment of eligible participants, materials, intervention delivery, program monitoring, data management, and overhead, were determined by prospective micro-costing and summarized for each intervention group. Prospective micro-costing methods tracked personnel time and materials using time logs and invoices, and valued them with local unit prices. Materials were office supplies, phone calls, printing, fecal immunochemical test (FIT) kits, FIT lab fee, and postage. Since all interventions require the same research processes including identification and recruitment of participants, staff training, general management and monitoring, and materials, costs of these activities were averaged across three intervention groups to avoid

penalizing an intervention thus equalizing random factors that might have caused costs to vary between interventions. Intervention delivery costs such as personnel time and equipment were directly measured based on the resources required for the alternative phone and web interventions. The total cost used in the cost-effectiveness analysis included the personnel time cost, the material cost, and the overhead cost. Overhead costs, such as office space and utilities are difficult to allocate to specific services such as screening promotion for breast and colorectal cancer. Following the practice of previous studies (7), overhead rate was calculated as 30% of the total direct cost. Intervention development cost was estimated elsewhere (25), but excluded from the cost-effectiveness analysis, as it was considered a sunk cost, i.e., the cost would not be incurred in future implementations of the intervention. All costs were inflated to 2016 U.S. dollars by the U.S. consumer price index – medical care component (http://data.bls.gov) (26).

Personnel time cost: Staff reported their minutes spent on each activity through monthly electronic time logs. The cost data collectors monitored time reports and followed up with staff who were delinquent in meeting time report deadlines. Time spent on informed consent, baseline interviews (except for determining eligibility and risk level), follow-up interviews, and chart reviews were research related costs and therefore excluded from the intervention cost. We multiplied the minutes per activity by the adjusted salary per minute (i.e., staff salaries adjusted for fringe benefit rates, available work time after adjusting for holidays and vacation days, and assuming an 85% productivity rate) (27) to calculate the personnel time cost of the individual staff. Personal time costs consisted of fixed time cost and variable time cost. Fixed time cost accounted for the time spent training phone counselors, setting up and test run the Website for the Web and Web + Phone interventions, and planning meeting for intervention roll-out. These activities occurred before intervention delivery and therefore remained fixed over a range of target population size. Activities required for each interaction with a participant of the target group were variable time and/or material costs. Those activities included identification, eligibility verification, enrollment of participants in interventions (exclusive of research costs related to human subjects protection/informed consent), time spent on Phone Counseling (recorded by call log), and time spent on Website (tracked by the Website when staff and participants logged on). When a call log was incomplete or missing, call time was imputed using multiple imputation (MI) with Markov Chain Monte Carlo method, considering age, race, marital status, education, employment status and income level of the participant. Ten imputed datasets were used to calculate the average parameter estimates of the regression model via the three MI procedures (imputation, analysis, and pooling).

Participant time cost: To calculate participant time cost, we multiplied participant interaction time reported by staff by the mean age adjusted hourly wage rates for full-time and part-time employed women. The federal minimum wage rate was assigned if employment status was missing or participant was unemployed.

Effect Estimation

Intervention effects, determined by receipt of either a mammogram or colorectal cancer screening (stool test or colonoscopy), were assessed at 6 months post-intervention by self-

report and medical record audit. Screening was considered positive in the “best estimate” approach if either self-report or medical records was positive (24). The primary screening effect measure was the average number of cancer screenings completed per participant, calculated by dividing the total number of screenings received (colorectal cancer + breast cancer) in each intervention group by the number of participants in the group. A secondary measure of effect was whether a participant received at least 1 screening (colorectal cancer or breast cancer). An additional effect measure, the receipt (0/1) of both screenings (colorectal cancer + breast cancer), is available in the Supplementary Table S1. Intent-to-treat (ITT) was used as primary approach to evaluate effectiveness in each group, whereby all participants were included in the analysis (28). Intervention effects were computed using odds ratios estimated from a binary logistic regression controlling demographic and other theoretically based confounders from the original study (24). To account for uncertainty in regression estimations, point estimates and lower and upper 95% confidence intervals of odds ratios indicated the variation in cost-effectiveness. Two secondary analyses were conducted to account for uncertainty in the estimation of intervention effects, considering attrition in the study. For the “best estimate” analysis, only participants with available follow-up data (self-report interview or medical record data) were included. In addition, we performed MI to estimate screening status for participants who were both lost to interview follow-up and missing medical record data. MI has the advantage of accounting for the uncertainty associated with both the missing data and other parameters in the imputation model (29). The same variables from the original randomized controlled trial were included in this imputation to optimize specification of the imputation model. Thirty datasets were imputed to accommodate the percentage of missing values as rule of thumb (29).

Cost-Effectiveness analysis

To identify the most cost-effective intervention to increase cancer screening compliance, we sequentially compared Usual Care to the Phone group, the Phone group to the Web group, and the Web group to the Web + Phone group using the incremental cost-effectiveness ratios (ICERs) computed by dividing the incremental cost by the incremental effect between pairs of study groups. Supplemental sensitivity analyses were conducted by varying the perspective of costing and other assumptions including overhead rates and cohort size. We did not discount costs and effects due to the relatively short approximately 6-month period between the intervention and follow-up.

Nonparametric bootstrapping with 1000 replicates of cost and effect was used to estimate the 95% confidence intervals for the ICERs. We derived a cost-effectiveness acceptability curve (CEAC) from bootstrapped results to show the probability that an intervention was more cost-effective than its comparator. Net benefit regression analysis was used to control unbalanced covariates among groups and to construct a cost effectiveness acceptability curve which shows the likelihood of an intervention being cost-effective under given hypothetical willingness to pay for an additional screening per woman. Microsoft Excel 2013 and SAS version 9.4 (SAS Institute, Inc., Cary, North Carolina, USA) were used in the study.

RESULTS

Participants' characteristics by intervention group were previously reported (24). In summary, most of the participants were white, had more than high school education, had a total combined yearly household income before taxes of more than $30,000, considered themselves at the same level or less than their age-adjusted risk for breast cancer, and had received a healthcare provider recommendation for a mammogram (24). More women in the Web group visited doctors 3 or more times; more women in the Web and Web + Phone groups were obese and limited their activities due to depression.

Table 2 shows the cost of each intervention related activity by intervention group, where the usual care group is omitted because there was no measured cost. Cost to identify and recruit eligible participants encompasses more than half (53-63%) of the total direct cost in each intervention group. Cost of intervention delivery accounts for as little as 9% of the total direct cost in the Phone group, and up to 25% in the Web + Phone group. Participants spent very little time related to recruitment and intervention activities, so participant cost as a percentage of total cost ranged from only 0.2% in the Phone group to 0.9% in the Web + Phone group.

Table 3 presents average cost and number of screening tests done per participant. The Phone intervention was the least costly and the second most effective. The Web intervention was less effective than the phone intervention at an increased cost (strong dominance), and therefore the Web intervention was excluded from consideration in the final cost-effectiveness computation. Under ITT analysis, lost follow-ups were included and the average number of screening tests done was estimated by intervention group using model adjusted odds ratios. With ITT base case estimates, the Phone intervention was cost effective at $300 per additional screening test compared to usual care. Web + Phone costs $1464 per additional screening test achieved compared to the Phone only intervention. With the higher model adjusted estimates, ICERs were similar to the base case analysis. However, the cost per additional screening test with Phone was more than double ($739) with the lower model adjusted estimates, while Web + Phone was no longer cost-effective. In best estimate analysis where patients lost to follow up were excluded, the ICER of the Phone intervention was about $766. The ICERs of Phone and Web + Phone interventions increased to $880 and $5,486 respectively with intervention effects estimated using MI for missing data.

Figure 1 plots 1000 simulated replicates of the cost and effect differences between the Phone intervention and Usual Care from primary ITT analysis using model adjusted estimates. The variation in cost is very limited due to the small portion of variable costs vs. fixed costs. The 95% CI of the ICERs comparing the Phone intervention to Usual Care ranges from $283 to $320. A detailed explanation and interpretation of the scatterplots on the cost-effectiveness plane is available in the appendix. Controlling for unbalanced characteristics among different groups in net benefit regression analysis showed similar results. CEAC shows that the probability of Phone intervention being cost-effective at the base case ICER ($300) is 50%. However, the probability goes up to 90% when decision makers are willing to pay $312 for each screening test completed (Supplemental Figure 2). The scatterplots on the cost-effectiveness plane comparing the Phone intervention and the Web + Phone

intervention shows a negative lower 95% confidence interval, which means the Web + Phone intervention can sometimes be less effective than the Phone intervention (Supplemental Figure 3). Supplemental Figure 4 also shows the probability of Web + Phone intervention being more cost-effective than Phone intervention at the base case ICER ($1,464) is 50%, and willingness to pay threshold needs to go up to $3,000 to increase the probability up to 80%.

Table 4 presents ICERs for the percentage of participants who received at least 1 cancer screening. With ITT base case model adjusted estimates, the Phone intervention costs $421 to have an additional person undertake screening compared to Usual Care, and it was the only cost-effective intervention among all three. Overall, the trend and pattern of ICERs observed in table 4 was similar to table 3. Generally, costs were higher to get an additional person screened than to have additional screening completed. In supplemental analyses (Supplemental Table S1), the percentage of participants who received both screenings was evaluated as an alternative outcome indicator. It costs $1039 to get 1 person screened for both breast and colorectal cancer with the Phone intervention compared to Usual Care, while the Web + Phone intervention costs $1273 more than Phone alone with base case model adjusted estimates.

Results of supplemental cost-effectiveness analyses are available in Supplemental Table S2. Cost-effectiveness analysis from a payer's perspective excluded costs incurred by participants. Due to the minimum participants' time spent on the intervention, the results were similar from both the participant plus payer's perspectives and the payer perspective, and the CEACs are almost identical (supplemental Figure 5). The sensitivity of the cost-effectiveness ratios to the assumed overhead rate of 30% of direct cost was evaluated with one-way sensitivity analysis, using overhead rate range of 0-40%. Varying overhead rate shows marginal increased ICER as overhead rate increases. To assess potential economies due to spreading fixed costs, we simulated results for up to 5000 eligible women per intervention group. Expanding the intervention increases the cost-effectiveness of the Phone intervention. With a larger cohort of 5000 in the target population, the simulated cost per additional screen declined to $239. Although the average cost to deliver one Web intervention dropped below the cost of the Phone intervention, the Web intervention was weakly dominated by the Phone intervention because it cost more to add another screening when compared to Usual Care ($603). Average fixed costs and ICERs may be reduced by expanding a "real world" programs to larger target populations as shown in the sensitivity analysis. In that case, the ICER declined by 20% as the cohort was increased from 173 to 5000 participants.

DISCUSSION

This study provides evidence of the cost-effectiveness of traditional Phone Counseling and an innovative tailored interactive Web-based intervention for promoting both breast and colorectal cancer screenings. Results show that targeting multiple cancer screening improves cost-effectiveness of an intervention. Our study also finds that: 1) the Phone intervention was the most effective strategy and incurred the lowest cost to deliver; 2) the Web intervention was less effective and more costly than the Phone intervention; and 3)

although the Web + Phone intervention was more cost-effective than Web intervention, it was still more costly and less effective than Phone intervention alone. The use of alternative effectiveness measures (the average number of screens completed [colorectal cancer plus breast cancer] and the receipt of at least one screening test [colorectal cancer or breast cancer]) did not change the order of cost-effectiveness ratios and the Phone intervention was still cost-effective but at a much higher cost. These findings were consistent with our conclusions in a prior manuscript that focused only on women non-adherent to colorectal cancer screening (30).

Economies of scope can be achieved by targeting screening promotion interventions to multiple cancers, where the cost of promoting two or more screenings is less than that of promoting each separately. A previous economic evaluation (7) divided the cost of intervention by the number of tests needed by the study subgroups, e.g. women may need both breast and colorectal cancer screening whereas men may only need colorectal cancer screening. Alternatively, we accounted for the efficiencies associated with simultaneous promotion of two tests by aggregating the two cancer screening tests completed as an overall measure of effectiveness for each eligible woman. In a prior cost-effectiveness study evaluating the same COBRA interventions promoting colorectal cancer screening alone (30), the Phone intervention was cost-effective and cost $995 per additional person screened compared to the no intervention (usual care) group. Our current analysis found that the Phone intervention cost 23% less per cancer screen achieved by the target population compared to Usual Care, and the additional cost for one more screening test completed declined by more than half to $421. The observed cost efficiency suggests that targeting more cancers may further improve the cost-effectiveness of cancer screening interventions, which warrants further investigation.

Chirikos et al. (2004) reported cost-effectiveness of the Cancer Screening Office Systems (SOS) intervention that simultaneously targeted breast, cervical and colorectal cancer screening. Using colored stickers in the medical chart to remind physicians of patients' cancer screening status, SOS was a low-cost and cost-effective intervention. Compared to SOS, COBRA Web and COBRA Web + Phone interventions were more costly partially due to the nature of tailoring that requires longer time to deliver, and partially due to more efforts to find and recruit non-adherent women compared to relatively passive recruitment of women visiting a primary care clinic. When behavioral interventions are adapted to a real-world setting, certain efforts are still needed to identify the target population. SOS adopted an "in reach" approach to identify eligible participants by a cancer-screening checklist completed by patients, which was much less costly then medical record review outreach in this study.

Another study reported the cost-effectiveness of an intervention to promote breast and cervical cancer screenings among Korean American women (31). The intervention provided individually tailored health information, as well as health literacy group education, telephone counseling, and navigation assistance delivered by trained community health workers (CHWs). Compared to the control group, the ICER was $236 per screening. Since participants were recruited by CHWs, the recruitment and training costs comprised 43% of the total intervention delivery costs. In our study, it cost $135 to recruit each eligible patient,

accounting for 63% of the total cost of the Phone intervention. Therefore, a more efficient recruitment approach based on an accurate EMR for example, may significantly improve the cost-effectiveness of the interventions.

Phillips and colleagues (32) assessed the cost effectiveness of personalized letters, automated telephone calls, and both on breast cancer and colorectal cancer screening in a pragmatic, randomized controlled trial. Both personalized letters and automated telephone calls were low-cost interventions since there was no direct personal interactions. Researchers reported $0.92 per participant for automated telephone calls, much less than personalized letters ($2.36 per mammography mailing and $7.17 per colorectal cancer letter and FIT kit). ICERs were reported separately for breast cancer and colorectal cancer. For breast cancer, automated telephone calls dominated personalized letters, while the combination cost was $15.73 for an additional participant screened. For colorectal cancer, it cost $210.6 to screen an additional participant with automated telephone calls compared to personalized letters, while the incremental cost for the combined intervention was only $12.43 when compared to automated telephone calls. Unfortunately, since no outcome measure of both cancer screenings was reported, we were unable to compare our results to this study. The researchers identified eligible participants through electronic practice management system, which avoided the high recruitment costs in our study.

Lynch et al. (2004) reported that an outreach intervention with a tailored letter and tailored phone call cost $818 in 2000 US dollars for one additional woman screened for both cervical and breast cancer. The ICER estimate would be much lower if they measured the outcome as the number of screening tests conducted per participant, because the screening rate of both Pap smear and mammography was double the rate achieved in usual care. Since our study examined promotion of screening for colorectal cancer and breast cancer, it presented a greater challenge than promotion of cervical cancer screening and mammography. The Lynch et al. study was conducted in a health maintenance organization (HMO) setting so participants and costs in an integrated health care delivery system might be different from those in the community. However, their intervention cost was comparable to ours, when adjusted for inflation. Evidence shows that recruitment costs are highly variable. Recruitment activities such as participant identification, marketing and outreach may be needed to implement or disseminate an intervention into a real-world setting. The costs of recruitment can be affected by research-related issues such as subject identification and obtainment of consent, so it is important to exclude research-related costs (e.g. informed consent) and to include only costs that would be required in replication (e.g., subject identification) (33). Compared to previous studies, the recruitment cost per participant in our analysis is on the high end due to the staff-time required for active outreach and recruitment. Passive recruitment from convenient samples using automated process may significantly reduce recruitment costs but may not be effective for a low-income and isolated community.

High attrition rates have been a common challenge in RCTs of health behavioral interventions (34). Missing values can occur in both cost data and health outcome data, which lead to bias if those lost-to-follow-up cases are systematically different from those with fully observed information. According to the intention-to-treat principle, enrolled participants should be analyzed according to which group they were originally assigned

(35), which allows researchers to draw unbiased conclusions regarding the effectiveness of an intervention. To assume appropriate screening rates for each study group including those who were lost to follow-up, logistic regression model adjusted odds ratios comparing each intervention to Usual Care for obtaining either a mammogram or colorectal cancer screening, or both a mammogram and colorectal cancer screening were obtained from the COBRA trial (24). Odds ratios of the two screening outcomes were later converted to percentages and used to calculate the average number of screening tests and the percentages of women who completed at least 1 screening test. With 95% CI of the odds ratios, two additional scenario analyses with lower and upper estimates other than base case were performed. As table 3 showed, ICER of the Phone intervention compared to Usual Care can be as high as $739 per additional screening test done with lower model adjusted estimate, which was closer to the ICER from best estimate analysis but lower than the ICER with multiple imputation estimates. The wide range of ICERs suggest potential variations of cost-effectiveness of the interventions.

There are several limitations in the current study. We evaluated only the short-term endpoint of additional screening test performed as our outcome, instead of following the participants for long-term outcomes such as morbidity or mortality. Therefore, we did not fully capture all cost and effectiveness across the cancer care continuum. However, based on the evidence that appropriate cancer screening is cost-effective in modeling studies extrapolated to life-time span (Rice 2019; Edwardson 2016; Wilson 2015; Hees 2014), it is appropriate to focus on the relative cost-effectiveness of alternative means to increase the screening rate among non-adherent individuals. In addition, 26.6% of the participants were lost to follow-up in this trial, which raises the question of selection bias due to attrition. Chi-square tests between the missing and non-missing cases on baseline characteristics show mostly insignificant differences except for age, recruitment site and reported barriers to mammography. To further assess the impact of high attrition, we incorporated several approaches to account for uncertainty in the screening status of those lost to follow-up. Due to the limits of accurately measuring overhead costs, we assumed a 30% overhead rate and tested the range from 0 to 40%. The basic results were not altered over this range of estimates.

CONCLUSION

The tailored Phone counseling was the most cost-effective intervention compared to the Web or Web + Phone interventions. To improve the cost-effectiveness of screening promotion interventions, future researchers and decision makers should consider bundling multiple cancer prevention services to achieve economies of scope. Disseminating the intervention programs to larger populations will also improve cost-effectiveness by lowering the intervention cost per participant. Finally, developing a more efficient approach to identify and recruit the target populations can be the main driver for cost-reduction.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Prevention Relevance Statement:

This study informs researchers, decision makers, healthcare providers and payers about the improved cost-effectiveness of targeting multiple cancer screenings for cancer early detection programs.

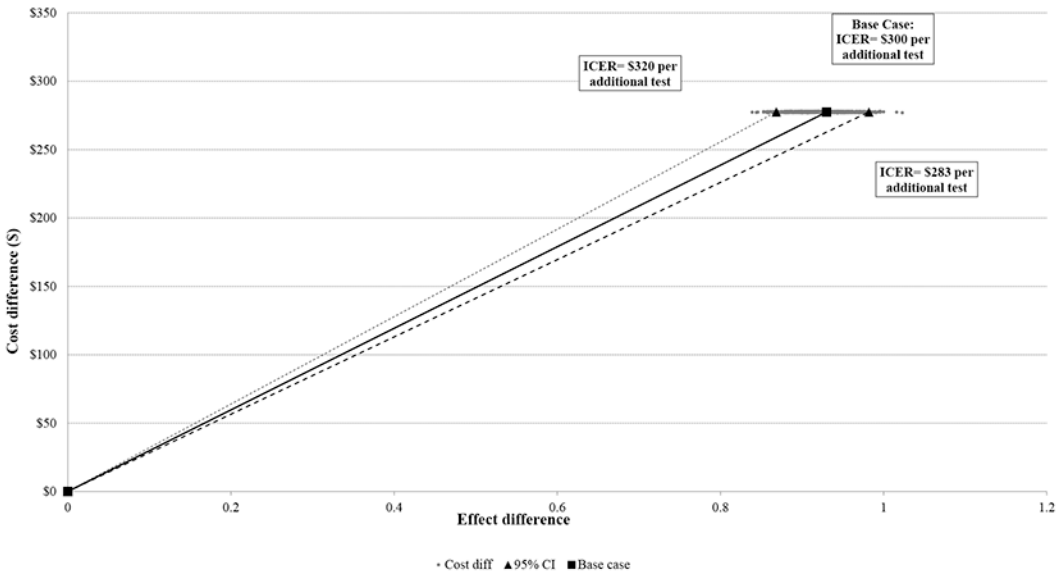

Figure 1.

Cost and Effect difference for Phone vs. Usual Care. Figure 1 plots 1000 simulated replicates of the cost and effect differences between Phone intervention and Usual Care from primary ITT analysis using model adjusted estimates on a cost-effectiveness plane.

Table 1.

Baseline Characteristics by Randomized Group

Baseline Characteristics Number (%) or Mean (SD)	Total Sample (n=692)	Web (n=180)	Phone (n=168)	Web + Phone (n=167)	Usual Care (n=177)	P value
Age, mean (SD)	58.7 (6.0)	59.5 (6.2)	58.6 (6.0)	58.0 (5.8)	58.6 (6.1)	0.1243
Health site						0.6089
Regenstrief	134 (19.4)	31 (17.2)	32 (19.1)	38 (22.8)	33 (18.6)	
Community	558 (80.6)	149 (82.8)	136 (80.9)	129 (77.2)	144 (81.4)	
Highest education						0.6182
High school graduate or less	199 (28.8)	51 (28.3)	45 (26.8)	56 (33.5)	47 (26.7)	
Some college	297 (43.0)	83 (46.1)	69 (41.1)	68 (40.7)	77 (43.8)	
4 year college graduate to graduate degree	195 (28.2)	46 (25.6)	54 (32.1)	43 (25.8)	52 (29.6)	
Race						0.1495
Black or African American	78 (11.3)	23 (12.8)	16 (9.5)	22 (13.2)	17 (9.6)	
White or Caucasian	587 (84.8)	153 (85.0)	149 (88.7)	134 (80.2)	151 (85.3)	
Asian, Pacific Islander, or Other	27 (3.9)	4 (2.2)	3 (1.8)	11 (6.6)	9 (5.1)	
Married or living with a partner	384 (55.7)	91 (50.6)	106 (63.1)	91 (54.5)	96 (54.9)	0.1217
Total combined yearly household income before taxes						0.1501
$30,000 or less	243 (36.4)	72 (41.6)	51 (30.9)	66 (40.5)	54 (32.3)	
$30,001 - $75,000	262 (39.2)	66 (38.2)	75 (45.5)	56 (34.4)	65 (38.9)	
$75,001 or above	163 (24.4)	35 (20.2)	39 (23.6)	41 (25.2)	48 (28.7)	
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 (%)	293 (42.8)	92 (51.4)	65 (38.7)	71 (42.8)	65 (37.8)	**0.0397**
Body Mass Index (BMI)						**0.0091**
Underweight / Normal	171 (25.8)	37 (21.4)	47 (29.4)	41 (25.6)	46 (27.2)	
Overweight	180 (27.2)	47 (27.2)	47 (29.4)	29 (18.1)	57 (33.7)	
Obese	311 (47.0)	89 (51.5)	66 (41.3)	90 (56.3)	66 (39.1)	
Total number of self-reported health problems, mean (SD)	1.9 (1.8)	2.1 (1.8)	1.7 (1.7)	1.8 (1.6)	1.7 (1.6)	**0.0250**
Does depression limit your activities? n (%) yes	61 (9.0)	19 (10.7)	11 (6.8)	24 (14.5)	7 (4.0)	**0.0048**
Perceived age-adjusted risk for breast cancer, n (%)						0.7415
About the same or not sure	424 (61.4)	109 (60.6)	102 (60.7)	109 (65.7)	104 (58.8)	
Higher risk	54 (7.8)	15 (8.3)	15 (8.9)	8 (4.8)	16 (9.0)	
Lower risk	213 (30.8)	56 (31.1)	51 (30.4)	49 (29.5)	57 (32.2)	
Mammography stage, n (%)						0.6352
Pre-contemplation	356 (51.5)	90 (50.0)	82 (48.8)	86 (51.5)	98 (55.4)	
Contemplation	336 (48.5)	90 (50.0)	86 (51.2)	81 (48.5)	79 (44.6)	
Has doctor or HCP suggested you get a mammogram? n (%) yes	622 (90.5)	158 (88.8)	158 (94.1)	143 (86.7)	163 (92.6)	0.0771

Baseline Characteristics Number (%) or Mean (SD)	Total Sample (n=692)	Web (n=180)	Phone (n=168)	Web + Phone (n=167)	Usual Care (n=177)	P value
Have any of your close blood relatives (parents, sisters, brothers, children) had breast cancer? n (%) yes	120 (17.3)	25 (13.9)	32 (19.1)	36 (21.6)	27 (15.3)	0.2171
Have 1 or more close blood relatives (parents, sisters, brothers, children) had colon cancer? n (%) yes	79 (11.4)	13 (7.2)	17 (10.1)	21 (12.6)	28 (15.8)	0.0711
Cancer and Cancer Screening Beliefs						
Fatalism	20.9 (7.0)	20.6 (6.4)	21.2 (7.6)	21.2 (7.1)	20.9 (6.9)	0.8944
Fear	22.7 (7.0)	22.7 (7.5)	22.5 (7.5)	23.5 (7.8)	22.2 (7.6)	0.5026
Susceptibility to breast cancer	6.3 (2.3)	6.4 (2.3)	6.1 (2.4)	6.3 (2.4)	6.3 (2.2)	0.5675
Benefits of mammography	13.3 (3.0)	13.7 (2.8)	13.2 (3.1)	13.0 (3.2)	13.3 (2.9)	0.1797
Barriers to mammography	27.6 (7.3)	27.6 (6.7)	27.4 (7.9)	28.2 (7.4)	27.3 (7.0)	0.6518
Self-efficacy for mammography	41.0 (5.6)	40.9 (5.6)	41.6 (5.6)	40.5 (5.3)	40.9 (5.8)	0.3346
Knowledge for mammography	4.9 (1.7)	5.1 (1.7)	4.9 (1.7)	4.6 (1.6)	5.0 (1.7)	0.0689
Mammography outcome indicators						
Has self-report data	404 (58.4)	97 (53.9)	109 (64.9)	86 (51.5)	112 (63.3)	**.0242**
Has medical record data	412 (59.5)	97 (53.9)	107 (63.7)	106 (63.5)	102 (57.6)	.1771
Has either self-report or medical record (best estimate)	515 (74.4)	126 (70.0)	133 (79.2)	123 (73.7)	133 (75.1)	.2685

Note: Boldface indicates statistical significance (p<.05). The p-values for continuous variables are from the general linear model omnibus F test, and for categorical variables are from the omnibus Pearson chi-square test. HCP = health care provider. CRC = colorectal cancer.

Table 2.

Cost of the Interventions per Participant

Activity			Phone $US (SE)	Web $US (SE)	Web + Phone $US (SE)	p-value
Personnel Cost	Identification & Recruitment of Eligible Participants	Planning & Monitoring	54.80 (0)	54.80 (0)	54.80 (0)	N/A
		Data Management	13.79 (0)	13.79 (0)	13.79 (0)	N/A
		Screening Eligibility	66.38 (0)	66.38 (0)	66.38 (0)	N/A
	Staff Training		12.69 (0)	12.69 (0)	12.69 (0)	N/A
	Intervention	General Management & Monitoring	4.50 (0)	4.50 (0)	4.50 (0)	N/A
		Phone Intervention	16.71 (2.46)	----	16.60 (3.19)	<.0001
		Web Intervention	----	43.97 (0)	43.97 (0)	N/A
Material Cost	FIT Kit		1.41 (0)	1.41 (0)	1.41 (0)	N/A
	Other Materials		42.70 (0)	42.70 (0)	42.70 (0)	N/A
Total Direct Cost			213.04 (2.46)	240.24 (0)	256.84 (3.19)	<.0001
Overhead Cost			63.89	72.07	77.05	<.0001
Participant Cost			0.55 (1.33)	2.00 (2.44)	2.91 (3.22)	<.0001
Total Cost			277.47 (3.02)	314.31 (2.44)	336.80 (5.29)	<.0001

Note: SE – standard error.

Table 3.

Primary ITT analyses, best estimate analysis and multiple imputation for number of screening tests done.

	Group	Average Cost per Participant ($)	Incremental Cost per Participant ($)	Number of Screening Tests Done	Incremental Effect	ICER ($)	95% Confidence Interval ($)
Primary ITT Analyses							
Model Adjusted Estimates (Base Case)	Usual Care (N=177)	0.00	-	0.42	-	-	
	Phone (N=168)	277.42	277.42	1.35	0.93	299.66	(283, 320)
	Web (N=180)	314.31	36.89	0.78	−0.57	dominated	
	Web + Phone (N=167)	336.80	22.49	1.39	0.61	1464.12	(−5927, 679)
Model Adjusted Estimates (Lower 95% CI Estimate)	Usual Care	0.00	-	0.42	-	-	
	Phone	277.42	277.42	0.80	0.38	738.54	(629, 897)
	Web	314.31	36.89	0.45	−0.35	dominated	-
	Web + Phone	336.80	22.49	0.79	0.34	dominated	-
Model Adjusted Estimates (Higher 95% CI Estimate)	Usual Care	0.00	-	0.42	-	-	
	Phone	277.42	277.42	1.62	1.20	231.94	(222, 242)
	Web	314.31	36.89	1.46	−0.15	dominated	-
	Web + Phone	336.80	22.49	1.67	0.20	1155.33	(−59575, 661)
Secondary Analyses							
Best Estimate Analysis	Usual Care (N=131)	0.00	-	0.42	-	-	
	Phone (N=133)	277.42	277.42	0.78	0.36	766.15	(565, 1172)
	Web (N=125)	314.31	36.89	0.54	−0.24	dominated	-
	Web + Phone (N=118)	336.80	22.49	0.69	0.15	dominated	-
Multiple Imputation	Usual Care (N=177)	0.00	-	0.49	-		
	Phone (N=168)	277.42	277.42	0.81	0.32	880.51	(478, 5581)
	Web (N=180)	314.31	36.89	0.69	−0.12	dominated	
	Web + Phone (N=167)	336.80	59.38	0.82	0.01	5485.98	(−208, 193)

Note: A strategy is dominated when it is less effective and more costly than the comparator strategy. When a strategy is dominated, it is removed from the following computations of the ICERs.

Table 4.

Primary ITT analyses and best estimate analysis for at least 1 screening test done.

	Group	Average Cost per Participant ($)	Incremental Cost per Participant ($)	Percentage of Participants Screened (%)	Incremental Effect	ICER ($)	95% Confidence Interval ($)
Primary ITT Analyses							
Model Adjusted Estimates (Base Case)	Usual Care (N=177)	0.00	-	30.53	-	-	
	Phone (N=168)	277.42	277.42	96.41	65.88	421.10	(400, 441)
	Web (N=180)	314.31	36.89	55.79	−40.62	dominated	
	Web + Phone (N=167)	336.80	22.49	95.80	40.01	dominated	-
Model Adjusted Estimates (Lower 95% CI Estimate)	Usual Care (N=177)	0.00	-	30.53	-	-	
	Phone (N=168)	277.42	277.42	60.32	29.79	931.13	(811, 1096)
	Web (N=180)	314.31	36.89	32.40	−27.92	dominated	
	Web + Phone (N=167)	336.80	22.49	56.99	24.59	dominated	-
Model Adjusted Estimates (Higher 95% CI Estimate)	Usual Care (N=177)	0.00	-	30.53	-	-	
	Phone (N=168)	277.42	277.42	100.00	69.47	399.34	(382, 417)
	Web (N=180)	314.31	36.89	98.42	−1.58	dominated	
	Web + Phone (N=167)	336.80	22.49	100.00	1.58	dominated	-
Secondary Analysis							
Best Estimate Analysis	Usual Care (N=131)	0.00	-	30.53	-	-	
	Phone (N=133)	277.42	277.42	61.65	31.12	891.47	(786, 1034)
	Web (N=125)	314.31	36.89	40.80	−20.85	dominated	
	Web + Phone (N=118)	336.80	22.49	52.10	11.30	−6.22	-