

## A Randomized Trial to Increase Colonoscopy Screening in Members of High-Risk Families in the Colorectal Cancer Family Registry and Cancer Genetics Network

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### Abstract

**Background:** Individuals with a strong family history of colorectal cancer have significant risk for colorectal cancer, although adherence to colonoscopy screening in these groups remains low. This study assessed whether a tailored telephone counseling intervention can increase adherence to colonoscopy in members of high-risk families in a randomized, controlled trial.

**Methods:** Eligible participants were recruited from two national cancer registries if they had a first-degree relative with colorectal cancer under age 60 or multiple affected family members, which included families that met the Amsterdam criteria for hereditary non-polyposis colon cancer (HNPCC), and if they were due for colonoscopy within 24 months. Participants were randomized to receive a tailored telephone intervention grounded in behavioral theory or a mailed packet with general information about screening. Colonoscopy status was assessed through follow-up surveys and endoscopy reports. Cox proportional hazards models were used to assess intervention effect.

**Results:** Of the 632 participants (ages 25–80), 60% were female, the majority were White, non-Hispanic, educated, and had health insurance. Colonoscopy adherence increased 11 percentage points in the tailored telephone intervention group, compared with no significant change in the mailed group. The telephone intervention was associated with a 32% increase in screening adherence compared with the mailed intervention (HR, 1.32;  $P = 0.01$ ).

**Conclusions:** A tailored telephone intervention can effectively increase colonoscopy adherence in high-risk persons. This intervention has the potential for broad dissemination to healthcare organizations or other high-risk populations.

**Impact:** Increasing adherence to colonoscopy among persons with increased colorectal cancer risk could effectively reduce incidence and mortality from this disease. *Cancer Epidemiol Biomarkers Prev*; 23(4); 601–10. ©2014 AACR.

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### Introduction

Although widely considered as preventable, colorectal cancer remains a common and often fatal cancer. More than 140,000 men and women in the United States will develop colorectal cancer each year, and 50,000 will die from this disease (1). The lifetime risk for developing colorectal cancer is about 5%, but a family history of colorectal cancer substantially increases this risk; having a first degree relative with colorectal cancer increases the risk about 2-fold, but if the relative has colorectal cancer under age 60 or there is more than a single first-degree relative, the risk increases 3- to 6-fold (2–4). Moreover, the risk of developing colorectal cancer for the members of families with genetic predisposition to colorectal cancer, specifically Lynch syndrome, is approximately 9 times higher than for general population (5–8).

A family history of colorectal cancer also has a major influence on recommendations for colorectal cancer

screening. For average-risk populations without a family history of colorectal cancer, screening is recommended to begin at age 50 with any of several screening tests (annual stool tests, sigmoidoscopy every 5 years with or without a stool test, or colonoscopy every 10 years; refs. 9, 10). Surveillance increases with family history of colorectal cancer. It is currently recommended that first-degree relatives of patients with colorectal cancer under age 60 be screened with colonoscopy starting at age 40 or 10 years before the earliest colorectal cancer diagnosis in the family no less than every 5 years (9, 10). Because of their markedly increased colorectal cancer risk, members of families with Lynch syndrome are advised to have colonoscopy screening every 1 to 2 years starting at ages 20 to 25 or 2 to 5 years before the earliest colorectal cancer if it is diagnosed before age 25 (10). About 3% to 5% of the population is thought to fall into one of these high-risk groups (3, 11), but they represent a disproportionate number of incident colorectal cancer and colorectal cancer-related deaths, which magnifies the importance of screening adherence in these families.

Despite the established efficacy of endoscopy screening to reduce colorectal cancer incidence and mortality (12–15), adherence to colorectal cancer screening remains suboptimal even in these high-risk groups (16–20). The Family Health Promotion Project (FHPP) was a randomized, controlled trial to test the effectiveness of a telephone-based counseling intervention to increase adherence to colonoscopy screening in members of high-risk colorectal cancer families. The study design and results from the baseline survey have been described previously (17). We report here the primary outcome data for FHPP and the effect of the intervention on colonoscopy screening adherence.

## Materials and Methods

### Trial design overview

The FHPP was a multicenter, randomized, and controlled trial. Participants at increased risk for colorectal cancer, as described below, were recruited from two national cancer family registries, the Colon Cancer Family Registry (C-CFR) and the Cancer Genetics Network (CGN), between February 2005 and July 2006 (21, 22). Consenting participants completed a baseline survey and were randomized to receive either a tailored, one-time telephone-based counseling intervention (tailored telephone intervention) or a mailed packet. Participants were mailed follow-up assessments at 6, 12, and 24 months to assess screening behavior as well as participants' knowledge, attitudes, and beliefs about colorectal cancer screening and barriers to having screening (e.g., cost, no symptoms, busy, fear/anxiety about the test, and worry about the preparation; ref. 17). Questions on the baseline and follow-up surveys were adapted and validated from previous studies (17, 23–25). The primary outcome for the study was prevalence of colonoscopy screening in the two groups within the 24-month study period from randomization. This study

was approved by the Colorado Multiple Institutional Review Board (IRB #03-858).

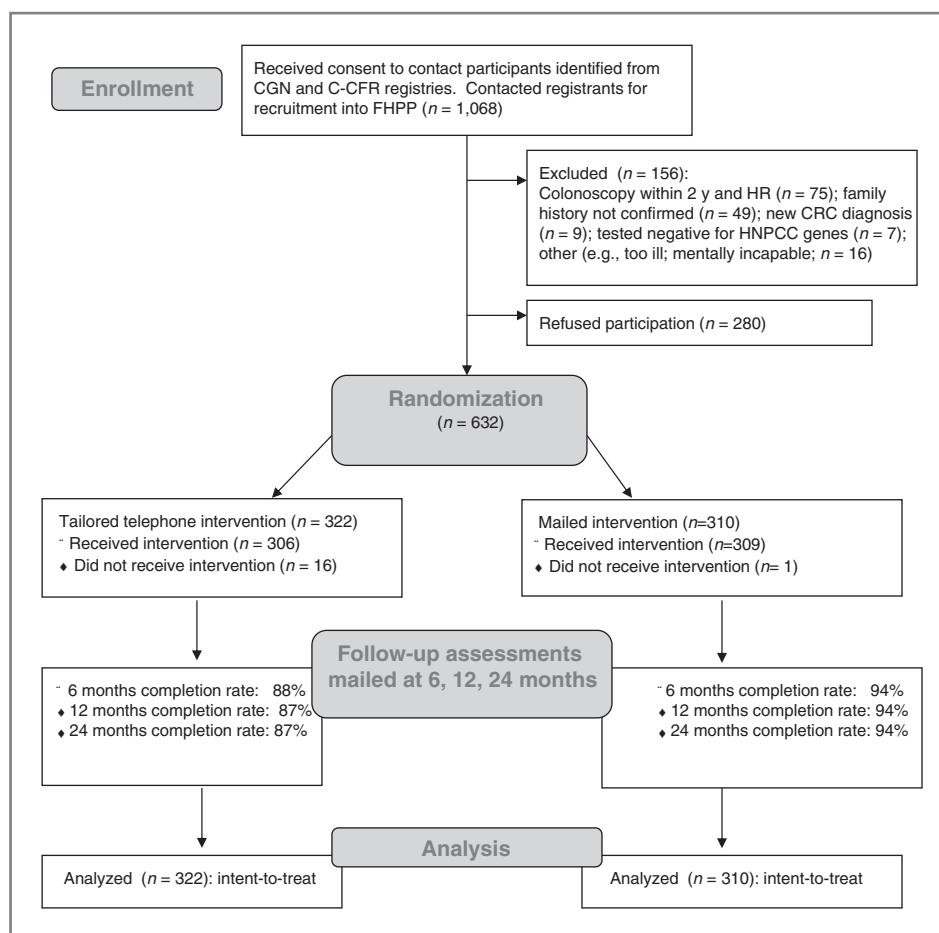
### Participants

Participants were recruited from eight C-CFR and three CGN registry sites; CGN centers: universities of Utah ( $n = 61$ ), New Mexico ( $n = 4$ ), and Colorado ( $n = 51$ ); C-CFR centers: universities of Arizona ( $n = 25$ ), North Carolina ( $n = 16$ ), Minnesota ( $n = 56$ ), Southern California ( $n = 5$ ), and Colorado ( $n = 38$ ), the Cleveland Clinic ( $n = 95$ ), Mayo Clinic ( $n = 95$ ), and the Fred Hutchinson Cancer Research Center ( $n = 185$ ). Eligible participants were unaffected with colorectal cancer, at least 21 years of age, English speaking, and at increased risk for colorectal cancer on the basis of their family history. Two classes of increased risk were defined. Participants from families that met the Amsterdam II criteria for hereditary non-polyposis colorectal cancer (HNPCC)—3 biologic relatives with colorectal cancer or other HNPCC-associated cancers, with one being a first-degree relative of the other two and at least two generations affected, and one cancer diagnosis under 50 years of age (7)—were classified as "HNPCC" participants. We used the term HNPCC for these participants because genetic testing had not been confirmed for these families, and the term Lynch syndrome is typically reserved for families with confirmed mutations in a DNA mismatch repair gene. Participants that had at least one first-degree relative diagnosed with colorectal cancer under age 60 or two or more first-degree relatives diagnosed with colorectal cancer at any age were defined as "high risk." Eligible participants must have been due for colonoscopy during the 24-month study period according to consensus guidelines for these populations. Because it is recommended that individuals from HNPCC families have colonoscopy every 1 to 2 years, all of these participants would have been due for colonoscopy during the 24-month period and thus eligible. The recommendation for high-risk participants is to have colonoscopy no less than every 5 years. Thus, high-risk participants who had a colonoscopy within the 3 years prior were excluded, as they would not have been due to have another colonoscopy during the study period.

### Recruitment and randomization

Upon receiving permission to contact participants from their respective registry site, FHPP staff at the University of Colorado Cancer Center contacted participants to recruit them into the study ( $n = 1,068$ ). Of the 1,068 subjects contacted, 156 were deemed ineligible and 280 refused participation for an overall response rate of 69% (632 of 912 eligible; Fig. 1). The 632 consenting participants, representing 533 families, completed the baseline survey and were randomized to receive either the tailored telephone counseling intervention ( $N = 322$ ) or the general mailed intervention ( $N = 310$ ). Block randomization was used to ensure equal distribution of participants across

Figure 1. CONSORT flow diagram for FHPP trial.



intervention groups by recruitment site, colorectal cancer risk level (HNPCC vs. high risk), and family unit to avoid experimental contamination.

### Tailored telephone counseling and mailed intervention

The components of the telephone counseling intervention have been described in detail previously (17). Briefly, the counseling intervention was delivered by trained interviewers using tailored messages based on participants' responses to the baseline survey and motivational interviewing techniques. The intervention was grounded in several theoretical models to promote behavior change, including the Health Belief Model (26–28), the Theory of Planned Behavior (29–30), and the Transtheoretical Model (32–34). The counseling intervention was conducted using computer-assisted telephone interviewing (CATI) software of the Survey Core of the University of Colorado Cancer Center. Upon establishing telephone contact, the interviewers began the session by eliciting the participants' readiness (stage of change) to have colonoscopy. On the basis of their response (1, ready; 2, ready but with some reservation; or 3, not ready), the interviewer appropriately engaged the participant in conversation about their perceived risk of colorectal cancer, risk-appropriate

screening guidelines, the pros and cons of colorectal cancer screening, and perceived barriers. Information from the participant's baseline assessment about these factors was incorporated into the interview, which allowed the interviewers to tailor the counseling session to focus on specific barriers and/or information gaps (e.g., knowledge of screening intervals specific to their risk level). At the end of the session, the interviewers engaged the participants in developing an individualized action plan that was appropriate, based on their readiness to be screened. Action items ranged from talking with their family members about the benefits of screening, to calling their provider to obtain a referral for colonoscopy. The average intervention session lasted between 20 and 30 minutes. Following the telephone counseling session, participants were mailed a summary of the issues discussed, including their personalized action plan that was extracted directly from the CATI software. Participants were sent a reminder postcard in the month before their colonoscopy due date.

Participants randomized to the mailed intervention group were mailed a letter stating the importance of maintaining a healthy lifestyle through exercise, diet, and routine screening for reducing risk of cancer and other chronic diseases, and were sent a *Choices for Good Health*

brochure, sponsored by the American Cancer Society. Participants were also encouraged to speak with their doctors about options for colorectal cancer screening, which may be different given their family history of colorectal cancer.

### Study outcome: colonoscopy screening

The primary outcome of the FHPP was the prevalence of colonoscopic screening at the end of the study period as reported on at least one of the follow-up assessments. Each assessment asked the participant whether (and when) they had had colonoscopy since the time of the previous survey. Participants who reported having had colonoscopy were asked to provide consent to obtain endoscopy and pathology reports to verify screening. Endoscopy reports were obtained for 98% of reported colonoscopies. Concordance between self-reported colonoscopies and endoscopy reports was 100%. Thus, we included all reported colonoscopies, including the five (2%) for which we could not obtain endoscopy reports in the analysis.

### Statistical analysis

To assess the effectiveness of randomization, we compared demographic characteristics between intervention groups using repeated measures models to account for familial clustering. These models were also used to assess any differences between groups with respect to baseline characteristics related to colorectal cancer screening, such as past screening history, knowledge of guidelines, intentions to screen, risk perception, and barriers to screening. McNemar's test was used to assess change in the percentage of participants who were adherent from baseline to 24 months within study groups (35). To account for the variability in the length of follow-up due to participant dropout or inability to contact, we used survival analysis techniques to test our main hypothesis of greater adherence to colonoscopy in the telephone counseling intervention group compared with the mailed intervention group at 24 months. Responses were censored at the time of colonoscopy or at the time of the last completed follow-up assessment. Cox proportional hazards methods (36) were used to assess the effectiveness of the telephone intervention while adjusting for any confounding variables identified. Regression parameters in the Cox models were estimated using a robust sandwich covariance matrix estimate to account for the familial clustering (37). An intent-to-treat approach was used; thus, all participants who were randomized were included in the analysis. Possible interaction effects by risk status were assessed. The sample size was established to enable detection of a relative difference in colonoscopy adherence of 15% overall between intervention groups at 24 months with 80% power.

### Results

A total of 632 participants were enrolled in the FHPP trial. Of the 322 participants randomized to the telephone intervention, 306 (95%) received the intervention (16 par-

ticipants could not be reached by phone within the allotted time frame per protocol), and 309 of 310 (>99%) participants in the mailed group received the mailed packet. Retention of participants over 24 months was greater than 90% overall: 87% in the telephone and 94% in the mailed intervention group.

Characteristics of study participants by intervention group are shown in Table 1. Twenty-five percent of participants ( $N = 125$ ) met the criteria for HNPCC and 75% ( $N = 467$ ) were classified as high risk. Approximately 60% of the participants were women, and the majority were ages 50 or older, Caucasian and non-Hispanic. The study population was generally well educated, and more than 90% had health insurance and a regular primary physician. A higher percentage of participants in the mailed intervention group had at least some college education ( $P = 0.02$ ), but the other demographic variables were balanced between the two intervention groups (Table 1). There were no significant differences between participants who consented compared with those who declined participation with respect to gender, age, race/ethnicity, or risk level.

Despite randomization, comparison of baseline attitudes, beliefs, and behaviors related to colorectal cancer screening revealed several significant differences between the intervention groups (Table 2). Participants in the mailed group were less likely than those in the telephone intervention group to report barriers to screening (63% vs. 71%;  $P = 0.048$ ) and more likely to be adherent with colorectal cancer screening (52% vs. 43%;  $P = 0.04$ ). There was also a trend toward a higher level of knowledge of screening recommendations in the mailed group (54% vs. 47%;  $P = 0.06$ ). More than 70% of the participants in both groups reported having at least one previous colonoscopy, but only about 50% said they intended to have a colonoscopy within the next 24 months. More than 80% of all participants recognized that they were at elevated risk for colorectal cancer.

In total, 328 participants reported having had a colonoscopy during follow-up. The proportion of participants who were adherent with colonoscopy at 24 months compared with baseline was assessed. In the mailed intervention group, adherence with colonoscopy at baseline was 52.1%, and it was slightly lower (49.8%) at 24 months. In the tailored telephone intervention group, the prevalence of adherence was 43.2% at baseline and increased by 11 percentage points to 54.0%. Eleven participants in the telephone and 10 in the mailed group had colonoscopy within 1 month of randomization, suggesting that these may have been scheduled before randomization. When stratified by risk level, we found that the HNPCC group had greater overall adherence at 24 months compared with the high-risk group, but the absolute difference in adherence from baseline to 24 months for the HNPCC and high-risk participants in the telephone intervention group was comparable (about 11 percentage points; ref. Fig. 2). There was no increase in colonoscopy

**Table 1.** Participant demographics by intervention group (N = 632)

Characteristic	Intervention group		P value for difference
	Tailored telephone (N = 322) N (%)	Mailed (N = 310) N (%)	
Gender			
Male	137 (43)	124 (40)	0.40
Age			
<40	19 (6)	17 (5)	0.50
40–49	88 (27)	64 (21)	
50–64	132 (41)	140 (45)	
65+	83 (26)	89 (29)	
Race			
African American	7 (2)	4 (1)	0.62
Caucasian	299 (93)	290 (94)	
Other	10 (3)	13 (4)	
Missing	4	3	
Ethnicity			
Hispanic	9 (3)	6 (2)	0.46
Non-Hispanic	307 (95)	298 (96)	
Missing	6	6	
Education			
Post college	59 (18)	58 (19)	0.02
College graduate	81 (25)	94 (30)	
Some college/tech	93 (29)	102 (33)	
High school	72 (22)	49 (16)	
Less than high school	14 (4)	6 (2)	
Missing	3	1	
Risk level			
HNPCC	81 (25)	84 (27)	0.91
High risk	241 (75)	226 (73)	
Household income			
\$70,000 or more	122 (38)	113 (36)	0.51
\$45,000–\$69,999	81 (25)	78 (25)	
\$30,000–\$44,999	52 (16)	54 (17)	
\$15,000–\$29,999	29 (9)	39 (13)	
< \$15,000	16 (5)	12 (4)	
Missing	22	14	
Have health insurance			
Yes	310 (96)	293 (95)	0.54
Have regular doctor			
Yes	291 (90)	291 (94)	0.11

NOTE: Due to rounding and missing data, percentages do not always add to 100%.  
Abbreviation: HNPCC, hereditary non-polyposis colorectal cancer.

adherence from baseline for either risk group among participants who received the mailed intervention.

Results from bivariate and multivariate analyses are shown in Table 3. In unadjusted bivariate analysis, using an intent-to-treat approach, the tailored telephone intervention was associated with a 24% increase in colonoscopy adherence at 24 months (HR, 1.24;  $P = 0.04$ ). Baseline factors that were significantly associated with greater adherence included having had a previous

colonoscopy, intent to have screening, appropriate colorectal cancer risk perception, and knowledge of risk-appropriate screening intervals. Not having a regular doctor was associated with lower adherence, as was having one or more perceived barriers to screening. Age, gender, education, insurance status, adherence at baseline, and risk level did not significantly predict adherence. After adjusting for significant covariates in multivariate analysis, we found that the tailored

**Table 2.** Baseline colorectal cancer screening behaviors, knowledge, and perceived colorectal cancer risk by intervention group ( $N = 632$ )

Baseline survey question	Intervention group		P value for difference
	Tailored telephone ( $N = 322$ ) N (%)	Mailed ( $N = 310$ ) N (%)	
Ever had colonoscopy	239 (74.2)	238 (76.8)	0.34
Adherent with CRC screening at baseline <sup>a</sup>	139 (43.2)	161 (51.9)	0.04
Intend to have colonoscopy in next 1–2 years	163 (50.6)	163 (52.6)	0.46
Knowledge of risk-appropriate screening recommendations <sup>b</sup>	151 (46.9)	166 (53.5)	0.06
Risk perception higher than others without family history	263 (81.7)	253 (81.6)	0.90
Barriers to CRC screening			
Reported one or more barrier	228 (70.8)	196 (63.4)	0.048
Median # of barriers (range)	2.00 (1–14)	2.00 (1–13)	

Abbreviation: CRC, colorectal cancer.

<sup>a</sup>Adherent for participants from HNPCC families (colonoscopy within past 2 years) and high-risk families (within past 5 years).

<sup>b</sup>For HNPCC, reported recommendation of "every 1–2 years"; for high risk, reported interval no less frequent than every 5 years [9, 10].

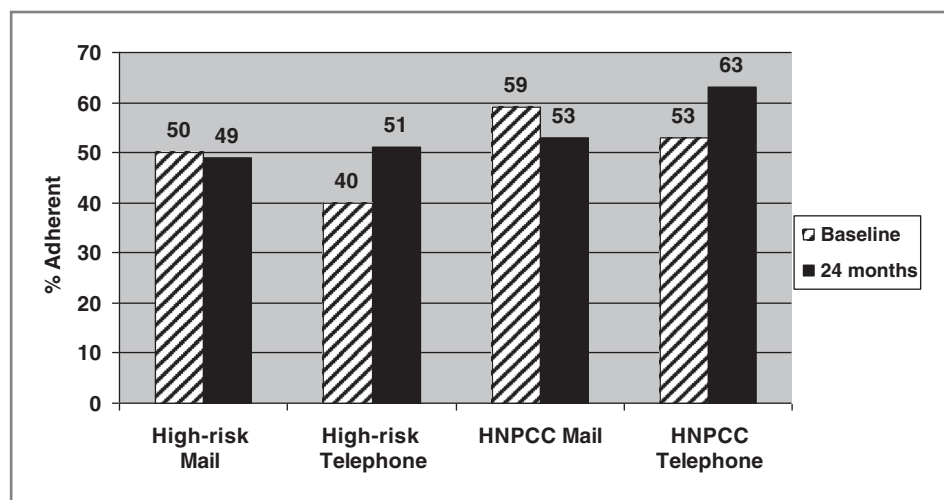
telephone intervention was associated with a 32% increase in colonoscopy adherence (HR, 1.32;  $P = 0.01$ ). Previous colonoscopy and intent to have colonoscopy in the next 1 to 2 years were also associated with increased adherence in the multivariate model.

## Discussion

Results from the FHPP trial demonstrate that a tailored educational and barriers counseling intervention delivered by telephone can effectively increase adherence to colonoscopy screening among members of high-risk colorectal cancer families. To our knowledge, this is the first randomized trial to successfully promote colonoscopy screening in high-risk populations that included individuals from HNPCC families. Efforts to increase both initial screening and maintenance of screening adherence in these groups are important, both because they have a

substantially increased colorectal cancer risk and because they continue to demonstrate relatively low screening adherence.

In this trial, we found that although more than 80% of our participants were aware that they were at increased colorectal cancer risk, less than 50% were adherent with recommended screening intervals at enrollment (Table 2), which is consistent with reports from previous studies (16–20, 38). One explanation for the low adherence at baseline in our participants seems to be a lack of knowledge of risk-appropriate screening intervals. As previously reported, only 22% of HNPCC and 52% of high-risk participants knew the recommended colonoscopy screening interval based on their family history (17). Given that a significant number of individuals in the general population are predisposed to colorectal cancer due to a strong family history (about 3% to 5%; refs. 3, 11) and the



**Figure 2.** Colonoscopy adherence by risk level (high risk vs. HNPCC) and intervention group at baseline and 24 months.

**Table 3.** Results from bivariate and multivariate analysis to assess the degree of screening compliance by baseline factors and intervention group ( $N = 632$ )

Subject characteristic	Bivariate analysis HR (95% CI) ( <i>P</i> )	Multivariate analysis <sup>a</sup> HR (95% CI) ( <i>P</i> )
Age (y)		
25–39	1.00	—
40–49	0.96 (0.52–1.76)	
50–64	1.14 (0.64–2.05)	
65+	1.28 (0.70–2.33)	
Male gender	0.86 (0.69–1.08)	—
Education	1.14 (0.88–1.48)	—
No college (vs. some college or more)		
No doctor	0.54 (0.30–0.96) (0.02)	—
No insurance	0.55 (0.27–1.14)	—
Risk group—HNPCC (vs. high risk)	1.15 (0.91–1.45)	—
Ever had colonoscopy	1.74 (1.27–2.38) (0.0003)	1.47 (1.06–2.04) (0.02)
Adherent at baseline	1.08 (0.87–1.34)	—
Plan on having colonoscopy in 1–2 years	2.98 (2.37–3.75) ( $<0.0001$ )	2.90 (2.30–3.65) ( $<0.0001$ )
Risk perception is higher than others without family history	1.73 (1.27–2.35) (0.0003)	—
Knowledge of risk-appropriate recommendations	1.33 (1.07–1.65) (0.01)	—
Reported barriers to CRC screening	0.73 (0.58–0.92) (0.007)	—
Any barrier (yes vs. no)		
Intervention arm—intensive	1.24 (1.01–1.55) (0.04)	1.32 (1.07–1.64) (0.01)

<sup>a</sup>Adjusted for all variables with a significance level of  $P < 0.05$  in the multivariate model.

persistent low rates of screening in these groups, interventions that even moderately increase screening have the potential to effectively reduce colorectal cancer morbidity and mortality in these families, and in the population at large.

By chance, the proportion of participants who were adherent with colonoscopy guidelines at baseline (but as required for eligibility, due for their next screening within 24 months) was significantly lower among participants randomized to the telephone intervention than in those in the mailed intervention (43% vs. 52%;  $P = 0.04$ ). Nonetheless, our results showed an 11% absolute increase in colonoscopy screening prevalence from baseline to 24 months (43% to 54%;  $P < 0.004$ ) among participants who received the telephone counseling intervention compared with essentially no change in adherence among participants randomized to the mailed group (52% vs. 50%;  $P = 0.56$ ). The multivariate analysis that accounted for the difference in baseline adherence showed that participants who received the telephone intervention were 32% more likely to have colonoscopy during follow-up than those in the mailed group.

The counseling intervention seemed to be effective in both the HNPCC and high-risk groups. Adherence to colonoscopy upon completion of the study was somewhat higher in the HNPCC group, which is important given their significant colorectal cancer risk, and consistent with previous reports of higher screening prevalence in this population following genetic education and counseling (39–42). However, the absolute difference in adherence was similar in both risk groups. This is encouraging, as an intervention that increases adherence in both risk groups would have wider applicability. It can be difficult to clinically distinguish the two risk groups without having a complete family history, which is rarely collected in clinical practice (43–46).

There have been few randomized studies of interventions to specifically promote colonoscopy adherence among individuals at increased risk for colorectal cancer due to family history, and none to our knowledge, that have included persons from HNPCC families (47). A study by Manne and colleagues (48) evaluated the effect of three increasingly intense behavioral interventions on colorectal cancer screening adherence in siblings of

colorectal cancer survivors: generic print materials versus tailored print materials versus. tailored print plus telephone counseling. Results from this study showed that although all three interventions increased adherence, adherence was significantly higher in each of the tailored groups compared with the generic group (25% and 26% vs. 14%, respectively), although there was no difference in adherence between the tailored print and tailored print plus telephone counseling groups. A second, smaller study by Rawl and colleagues (49) that compared the effect of two print interventions (generic vs. tailored) to increase colorectal cancer screening among siblings and children of colorectal cancer cases similarly demonstrated that both interventions increased adherence (21% and 14% at 12 months), but found no difference in adherence between the tailored and generic print groups. Finally, a trial by Glanz and colleagues (50) tested the effect of using face-to-face risk counseling (vs. general health counseling) to increase screening adherence among siblings of colorectal cancer cases. This intensive intervention resulted in a net change in adherence (above the general counseling group) of 13 and 11 percentage points at 4 and 12 months, respectively.

Variability across studies with respect to study population, screening outcome, intervention intensity, and mode of delivery make it challenging to directly compare results. For FHPP, we included participants who were adherent at baseline but were at risk for becoming non-adherent during the study period, whereas other studies specifically excluded these individuals (48, 49). We also limited our outcome to colonoscopy screening, where others have included additional colorectal cancer screening modalities (49, 50). In addition, our trial did not include a "tailored-print" arm with which to specifically compare our telephone intervention. Nonetheless, our finding of a net change in adherence of 11 percentage points in our telephone intervention group over that of our control group is similar to that reported in two previous trials (48, 50).

Taken together, with some exceptions, results from our study and other studies suggest that tailored interventions may be more effective in promoting screening in high-risk groups (47, 48, 50). Using tailored messages is particularly relevant when addressing populations of various risk profiles as we had in FHPP, and when attempting to promote both initial screening as well as adherence to recommended screening intervals, which differ depending on risk. It remains unclear as to whether print versus telephone delivery would be equally effective. The challenge to using a tailored approach in practice is having adequate information about the target population *a priori* such as family history and known barriers, which is often not available. One benefit of using a phone-based approach is the ability to assess risk, readiness, and barriers in real time that can be directly translated into tailored messages.

The FHPP study has many strengths, including a prospective, randomized, controlled design, high response

and retention rates, and validation of self-reported colonoscopies with endoscopy reports. The use of two NCI-funded registries allowed the identification of (HNPCC and high risk) participants with well characterized and updated family history information available. Having information about risk *a priori* allowed us to tailor the intervention to appropriately address issues of colorectal cancer risk and recommended screening intervals. Use of the CATI technology allowed the counseling intervention to be tailored in real time and importantly, to address any persisting barriers to screening. For example, for participants who shared that cost was an issue or that they did not feel that screening was necessary since they did not have symptoms (two of the most common barriers), the interviewers were able to counsel them on how to approach their provider to discuss payment options, and were able to immediately reinforce to participants that screening is most effective for preventing cancer before symptoms arise. These messages were included in the action plan that was discussed and reiterated in the follow-up letter. Finally, the use of motivational interviewing techniques allowed the interviewers to assess and tailor messages that were appropriate for participants' readiness to undergo screening (17).

Our study also has some limitations. Our participants were also mostly White, affluent, had health insurance, and higher education levels, and were all English speaking, which may limit generalization of our findings. Similarly, by virtue of their participation in the registries, our participants may be different than other high-risk individuals in that they may be more aware of their risk and the importance of screening, and therefore more motivated to undergo screening. It is possible that participants who had colonoscopy within a month of randomization had scheduled this before receiving the intervention. However, this number was small and comparable across groups; thus, it is unlikely that this significantly affected our results. Despite the overall large sample size, the smaller size of the HNPCC subset ( $n = 165$ ) limited the power to assess interactions. Finally, randomization did not result in the equal distribution of several important variables, including baseline adherence to colonoscopy. This may, in part, have been due to clustering of family members within intervention groups, who may have similar screening practices. This difference attenuated the effect of the intervention in that at 24 months the absolute screening prevalence in the two intervention groups was similar.

In conclusion, the FHPP trial demonstrated that a relatively brief but tailored telephone-based, education, and barriers counseling intervention can increase colonoscopy screening in persons at increased risk for colorectal cancer due to their family history. As designed, our intervention, which was tailored in real time by nonmedical interviewers, has the potential for broad dissemination into healthcare organizations or populations (such as high-risk registries) that have the capacity to identify persons at increased risk. Although our intervention effectively increased adherence, there remained a subset of



participants who were nonadherent, highlighting the need for continued efforts to identify strategies for improving adherence in these high-risk groups. These efforts may start with enhancing systems for identifying persons with familial risk, ensuring that providers are aware of risk-appropriate guidelines and enlisting patient navigators to assist patients who face significant barriers to screening. Eliciting patients' barriers, mutually identifying ways to overcome these, and developing an action plan for taking next steps may help to increase screening in these more resistant populations. Analyses are under way to identify specific components from our intervention that were most likely to increase colonoscopy adherence, which will inform the nature and viability of broader dissemination of this intervention.

### Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

### Disclaimer

The content of this article does not necessarily reflect the views or policies of the NCI or any of the collaborating centers in the CFRs, nor does the mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government or the C-CFR.

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