

7-2007

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Karen Glanz
Emory University

Alana D. Steffen
University of Hawaii at Hilo

Lauren Taglialatela
Kennesaw State University, ltaglial@kennesaw.edu

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Recommended Citation

Glanz, K., Steffen, A. D., & Taglialatela, L. A. (2007). Effects of colon cancer risk counseling for first-degree relatives. *Cancer Epidemiology Biomarkers & Prevention*, 16(7), 1485-1491. doi:10.1158/1055-9965.EPI-06-0914

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Cancer Epidemiology, Biomarkers & Prevention



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Effects of Colon Cancer Risk Counseling for First-Degree Relatives

Karen Glanz,¹ Alana D. Steffen,² and Lauren A. Tagliatalata^{1,3}

¹Rollins School of Public Health, Emory University, Atlanta, Georgia; ²Cancer Research Center of Hawaii, University of Hawaii, Honolulu, Hawaii; and ³Department of Psychology, Kennesaw State University, Kennesaw, Georgia

Abstract

Background: Individuals with a first-degree relative who has had colorectal cancer are at increased risk for colorectal cancer and thus can benefit from early detection. Tailored risk counseling may increase adherence to screening guidelines in these persons. The present study evaluated a culturally sensitive Colon Cancer Risk Counseling (CCRC) intervention for relatives of colorectal cancer patients.

Methods: A randomized trial evaluated personalized CCRC sessions with print materials and follow-up phone calls compared with a comparable General Health Counseling (GHC) intervention. One hundred and seventy-six siblings and children of colorectal cancer patients, living in Hawaii, were assessed at baseline and 4 and 12 months after intervention. Physician verification of colorectal cancer screening reports supplemented survey data.

Results: The CCRC intervention had a significant treatment effect at 4 months (13% greater increase than for GHC) that plateaued to a trend at 12 months. For those who were nonadherent at baseline, the CCRC led to a 17% net increase in screening adherence. Participants rated the CCRC intervention better than GHC for the amount and usefulness of new information.

Conclusions: Using a study design that compared risk counseling to an attention-matched and tailored control condition provided a rigorous test of CCRC that emphasized the relevance of family experience with colorectal cancer. The combination face-to-face, phone, and small media risk counseling intervention for people with a family history of colorectal cancer should be considered for adoption in health care and public health settings. (Cancer Epidemiol Biomarkers Prev 2007;16(7):1485–91)

Introduction

Colorectal cancer is the second leading cause of cancer death in the United States (1). In 2006, an estimated 148,610 people in the United States will be diagnosed with colorectal cancer, and 55,170 people will die from the disease (2). For the average person, lifetime risk of developing colorectal cancer is about 1 in 20. Approximately 10% to 15% of colorectal cancer occurs in individuals who have a first-degree relative (FDR) who has had the disease, and these persons have about twice the risk of the general population (3, 4). Risks are greater if the diagnosis of the FDR was before age 50, if the cancer was in the distal segment of the colon, and if there is also a second- or third-degree relative with colorectal cancer or other FDRs with other cancers (breast, ovarian, uterine, and prostate; refs. 3, 4).

Screening for colorectal cancer can significantly reduce morbidity and mortality and is recommended for average-risk persons age ≥ 50 years (5, 6). Despite its shown efficacy, screening is significantly underused. Although colorectal cancer screening uptake has increased recently, only about half of all adults age ≥ 50 years have completed any recommended test (7, 8).

Screening recommendations for people with a family history of colorectal cancer, but without hereditary syndromes such as hereditary nonpolyposis colorectal cancer or familial adeno-

matous polyposis, vary across published guidelines (9). Most guidelines recommend that screening should begin at an earlier age (usually age 40) and be repeated more often (5, 10). The guidelines that have been promulgated categorize persons by family history (number and closeness of relationships and age at diagnosis) and clinical symptoms (e.g., other cancers, polyps, and inflammatory bowel disease; ref. 9). For example, for people with a FDR diagnosed with colorectal cancer before age 60, colonoscopy beginning at age 40 is recommended (5, 10). Those with a history of polyps or inflammatory bowel disease should undergo early surveillance with colonoscopy and diagnostic follow-up (9), but those with a FDR diagnosed above age 60 should begin screening at age 40 using methods advised for average-risk persons beginning at age 50 (5). Recent data indicate that FDRs of colorectal cancer patients are more likely to be screened than those at average risk but that they are also significantly underusing screening (11, 12).

In the past few years, there has been growing attention in both research and practice to the issue of family history of colon cancer and its potential to help focus efforts to increase screening uptake (13–16). Understanding the link between family history and personal risk may be especially important in increasing perceptions of personal susceptibility (17) and risk salience (18). In one recently published study, closeness of the relationship of a person to his/her FDR with colorectal cancer had an indirect effect on screening intentions (19), which suggests that including information about an affected relative in colorectal cancer interventions may increase favorable attitudes and health behaviors related to screening.

Risk communication experiments have tested various ways to present colorectal cancer risk information using computer-based trials (20, 21), a worksite tailoring experiment (22, 23), and a trial of callers to the National Cancer Institute's Cancer Information Service (25). The study of Cancer Information Service callers found that tailored print materials were effective for promoting colorectal cancer screening in a non-high-risk audience but that multiple tailoring and retailoring

Received 10/31/06; revised 4/26/07; accepted 5/7/07.

Grant support: National Human Genome Research Institute grant R01 HG 01241.

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Note: This study was approved by the Institutional Review Boards of the University of Hawaii, Kaiser Permanente Hawaii, Hawaii Pacific Health (Kapiolani Hospital and Straub Medical Center), Kuakini Medical Center, Queen's Medical Center, and St. Francis Medical Center (Honolulu). The findings and conclusions of this study do not necessarily represent the views of these hospitals and/or their facilities or subsidiaries.

Requests for reprints: Karen Glanz, Rollins School of Public Health, Emory University, 1518 Clifton Road Northeast, Room 526, Atlanta, GA 30322. Phone: 404-727-7536; Fax: 404-727-1369. E-mail: kgglanz@sph.emory.edu

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doi:10.1158/1055-9965.EPI-06-0914

did not further increase screening rates (25). However, a worksite study found that print and/or telephone tailored messages did not improve risk perception or screening of increased-risk workers over time (23). Another large intervention study with tailored phone counseling, interactive barriers counseling, and follow-up mailings has been conducted (26), but the results have not yet been published.⁴ Up to now, results from studies focusing on family history as the focus of risk counseling have not been reported.

Given the high toll of colorectal cancer and the widespread underuse of early detection, it may be useful to focus screening promotion efforts on people with a family history of the disease. Past research has shown that both objective and perceived risk are associated with use of colorectal cancer screening (27, 28), and risk feedback and counseling interventions have been found effective for achieving more accurate cancer risk comprehension (29–31) and increasing adherence to mammography screening advice (28, 31). Tailored health communications that provide individualized information to the recipient (32) are more often read, remembered, and seen as personally relevant than are nontailored materials (33). Tailoring health messages to cancer risk factors and specific aspects of family history using small media (e.g., pamphlets and brochures) and/or one-on-one education is a promising yet unproven strategy for increasing recommended use of colorectal cancer screening (34). The current study addresses this evidence gap.

Materials and Methods

Design and Subjects. The study was a randomized trial where subjects were randomly assigned to receive either (a) Colon Cancer Risk Counseling (CCRC) or (b) General Health Counseling (GHC; control). Subjects were male and female siblings and children residing in Hawaii, ages ≥ 40 years, who had a family history of colorectal cancer in one FDR. The study was named FACETS, which stands for Family Cancer Education and Talk-Story Study. "Talk-Story" is an expression used in multicultural Hawaii and refers to a comfortable way to exchange information and ideas.

Colorectal cancer cases were identified through the Hawaii Tumor Registry, a population-based tumor registry. Index patients were excluded if a physician indicated that they were too sick or frail to participate, if they did not speak English, or if they had another FDR with colorectal cancer. Exclusion criteria for FDRs were (a) personal history of colorectal cancer, (b) non-English speaking, and (c) two or more FDRs with colorectal cancer. Risk information was obtained through the Hawaii Tumor Registry and baseline telephone interviews. Follow-up assessments were conducted at 4 and 12 months after intervention to assess the effect of the interventions on colorectal cancer screening adherence, risk comprehension, psychological adaptation, and other health behaviors.

Theoretical Foundation. The theoretical foundation of the intervention and evaluation used constructs from the precaution adoption process model (PAPM; ref. 35) and the transactional model of stress and coping (36). Both models are concerned with how individuals perceive threatening situations or hazards and what factors determine whether they take protective action or engage in adaptive coping behaviors. The PAPM, a stage model of behavior (35), provided the theoretical underpinnings for the experimental intervention strategies. The transactional model (36) offers a parsimonious conceptualization of moderating, mediating,

and outcome variables and guided the evaluation and measures.

Intervention. The CCRC was based on the PAPM. The first three stages of the PAPM involve beliefs about susceptibility to harm (e.g., risk of developing colon cancer): having heard of the hazard, believing in its likelihood for others, and acknowledgment of personal susceptibility. The fourth stage is the decision to take a precaution. The final stage is taking protective action (e.g., get screening; ref. 35). In the PAPM, personal experience is a particularly powerful stimulus to action (18). The CCRC intervention used tumor registry data about the index patient's cancer diagnosis and disease characteristics to illustrate personal risk and the benefits of screening (whether the index patient's cancer was detected through screening). During the later stages, beliefs about costs and benefits of action, practical steps for taking actions, and reminders are influential (35) and were incorporated into the CCRC experimental intervention. The CCRC intervention in this trial was developed to be culturally sensitive in the context of multiethnic Hawaii using data from our previous exploratory research (37), local images, and pilot testing to refine the intervention components.

The CCRC intervention was an individual face-to-face health counseling intervention with a nurse educator or trained health educator, tailored print materials, and two follow-up phone calls. The health counseling sessions lasted about 1 h. The nurse/health educator used a tabletop flip chart to review general information about colorectal cancer, risk factors, colorectal cancer screening modalities, and screening guidelines. Tailored, or personalized, print materials consisted of four items in a pocket folder: (a) personal risk profile with feedback about perceived benefits and barriers to screening, (b) family member (index patient) risk information, (c) personal screening recommendation chart, and (d) action planning form.

The follow-up phone calls occurred 3 weeks and 2 months after the counseling session. They included a review of action plans and their status, reinforcement of information about risk, and risk reduction options and further barriers counseling if needed. Positive reinforcement was provided to those who had taken appropriate screening actions. If the participant had been screened by the time of the follow-up calls, the call was used to discuss the results and answer any new questions.

The GHC control focused on health promotion actions related to diet, exercise, tobacco, and screening for cancer and cardiovascular risk. Like the CCRC intervention, it was tailored to subjects' reported behaviors and characteristics at baseline and was culturally appropriate. As in the CCRC, the GHC included tailored (personalized) print materials for participants and two follow-up telephone calls.

When more than one FDR in a family participated in either the CCRC or GHC counseling sessions, they were invited to have a joint session. However, this was not required if it was inconvenient for the participants. Follow-up telephone calls were made to each individual because it was not feasible to speak with more than one family member at a time by phone.

Procedures. Recruitment for the study was a multistep process involving (a) physician permission to contact the index patient, (b) contacting the index patient to determine eligibility of his/her FDRs and obtain their contact information, and then (c) inviting eligible FDRs to take part in the trial. The index cases are Hawaii residents diagnosed in 1997 to 2001 with pathologically confirmed colorectal adenocarcinoma. The protocol was approved by the Hawaii Cancer Commission, the University of Hawaii Institutional Review Board, and Institutional Review Boards at the six hospitals where the index patients had been treated.

Figure 1 displays two flow charts that summarize the recruitment process. We received the names of 1,612 index

⁴A.C. Marcus, personal communication.

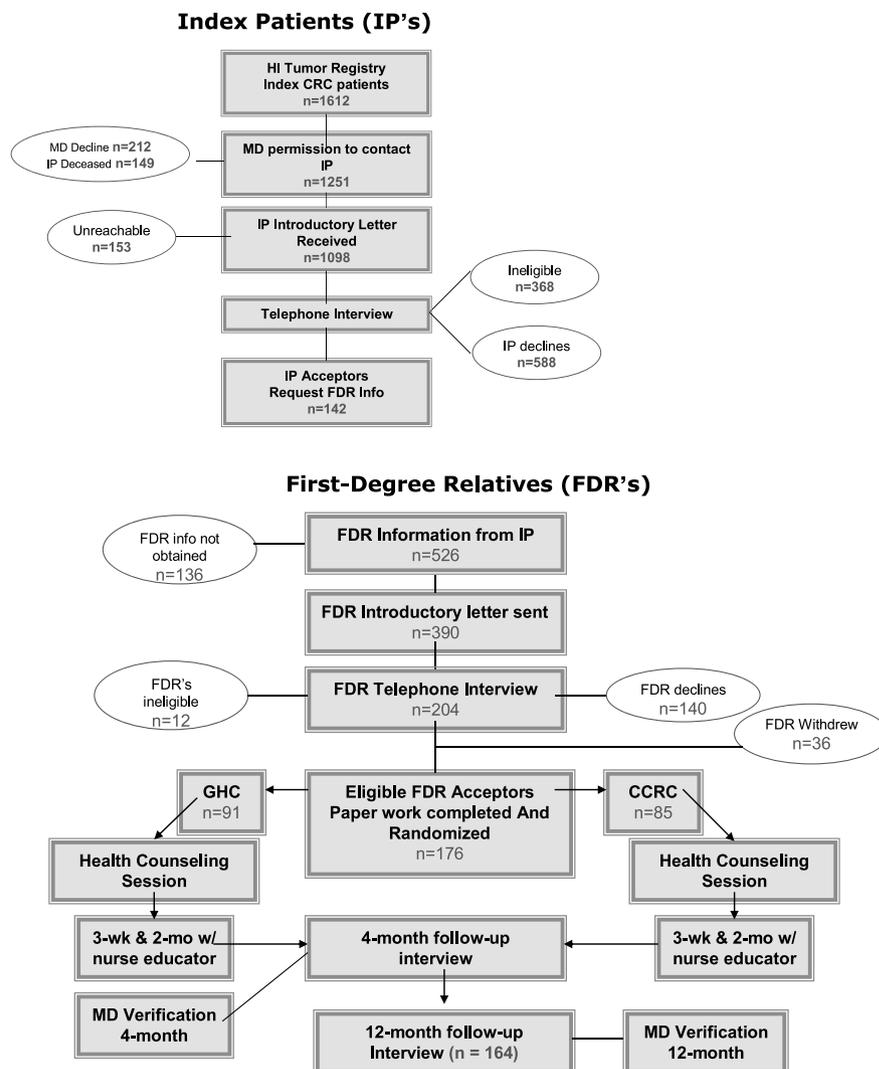


Figure 1. FACETS recruitment flow charts. CRC, colorectal cancer.

patients with colorectal cancer and were able to reach 1,098 (68.1%). Telephone interviews were completed with 958 index patients (87.2%), and 142 index patients who had 526 possibly eligible FDRs agreed to provide information about those relatives. Complete contact information was obtained for 390 FDRs (74.1%), and 204 of those relatives (52.3%) were eligible and completed a baseline telephone interview. In families with multiple FDRs, all those who were eligible and willing to participate were enrolled in the study.

Of those FDRs who were interviewed at baseline, 176 (86.3%) completed the consent process and were randomized to either CCRC (treatment group, $n = 85$) or GHC (control group, $n = 91$) and completed the counseling session and telephone boosters. One hundred and sixty-four FDRs (93.2% of those randomized) completed the 4- and 12-month assessments.

The index patients with participating FDRs were 59.3% male and 40.1% female and predominantly of Japanese ethnicity. Their mean age at diagnosis was 65.2 years and the median time since cancer diagnosis was 2.5 years. There were no significant differences in gender, ethnicity, age, or time since diagnosis between ineligible index patients, decliners, and those index patients who participated.

Measures. Index patient and disease characteristics, including index patient age at diagnosis, gender, ethnicity, location of cancer, history of diagnosis, stage at diagnosis, and treatment history, were collected from the Hawaii Tumor Registry. After

a FDR agreed to participate, a telephone interview queried his or her extended family history of cancer, personal history of cancer, bowel disease, and polyps. Demographic characteristics of the FDR assessed by telephone interview included age, gender, ethnicity of all four grandparents, education, income, marital status, and religious affiliation. Health care factors measured included health insurance coverage and source of regular care.

Risk level was an ordinal variable with three levels. Subjects were categorized into one of the three risk levels based on family history and personal risk factors. Colorectal cancer screening adherence, the primary outcome, was defined as a person receiving the appropriate screening test within the recommended time frame. The appropriate test for each individual was assessed based on their risk level, age, and self-reported doctor recommendation. Participants were considered risk level 1 if their relative, the index patient, was diagnosed at age ≥ 60 years, they had no known second-degree relatives with colorectal cancer, and they had no personal history of polyps or irritable bowel syndrome. Persons at risk level 1 and < 50 years were recommended to complete a fecal occult blood testing annually, unless advised to have more intensive screening by their doctor, and risk level 1 participants ≥ 50 years had a recommendation of flexible sigmoidoscopy every 3 years. Risk level 2 participants had either a history of polyps and/or a second-degree relative with colorectal cancer and no other risk factors. Risk level 3 was assigned to persons having either a personal history of irritable

bowel syndrome or their relative (index patient) had been diagnosed under the age of 60. All persons at risk level 2 were recommended to have a flexible sigmoidoscopy every 3 years, and for all persons at risk level 3, a colonoscopy every 3 years was the recommendation. A person was considered adherent if they reported having had the appropriate test (or a more intensive test) within the recommended time frame.

To verify self-report of colorectal cancer screening during the study, a survey was sent to participants' physicians. Physicians were asked to check the medical record for any colorectal cancer screening, and if it had been completed, for the date and results of fecal occult blood testing, flexible sigmoidoscopy, or colonoscopy screening tests. Physician surveys were sent at about the same time as the 4- and 12-month follow-up interviews. Twelve-month surveys were not sent if a participant dropped out (0.6%), did not have a current physician (1.2%), or if the physician responded to the 4-month survey that the participant was adherent (7.3%). The return rate was 98.2% for 4-month surveys and 94.6% of 12-month surveys returned. The κ s for agreement of respondent with physician were very good for flexible sigmoidoscopy and colonoscopy combined, ranging from 0.76 at 4 months to 0.68 at 12 months. McNemar's tests indicated some respondent overreporting (or physician underreporting) for fecal occult blood testing. Because we did not find any systematic measurement error, we used participant self-report data on adherence in the full analysis.

Psychosocial variables in the study, based on Weinstein and Sandman's PAPM (35), were referred to as primary appraisals and secondary appraisals using terminology from Lazarus' transactional model of stress and coping (36). These variables used previously developed or adapted measures (28, 29, 38). The primary appraisal variables included hypothesized mediating outcomes: risk comprehension, cancer worry, and subjective experience. Secondary appraisals were assessed using items from Vernon et al.'s scales for efficacy of screening, worries and fears, or barriers, and self-efficacy, which have been found to have construct validity and acceptable internal consistency reliability (27). Family communication items assessed the frequency of discussing health concerns with family members (37). Knowledge measures were previously developed for a study we conducted and included an 11-item measure of knowledge about colon cancer and a 10-item measure of knowledge about cancer and heredity. The combined 21-item knowledge measure has internal consistency reliability of $\alpha = 0.79$.

We measured other health behaviors, including physical activity, smoking, alcohol intake, other cancer screening, and dietary behaviors, by previously published brief assessments (39, 40).

Reactions to the interventions were assessed by four questions asked on a survey at the end of both the CCRC and GHC counseling sessions. These items queried participants' perceptions of the amount of new information learned, usefulness of the information, helpfulness of personalized booklets, and rating of the nurse/health educator, each on a scale of 1 to 5, where 1 was the lowest score and 5 was the highest.

Statistical Methods. Preliminary analyses were conducted to assess treatment group equivalence and to examine characteristics of dropouts. Next, the main effects analysis was conducted for the primary outcome (adherence) and for five secondary health behavior outcomes. Mediator analyses were conducted and reactions to the interventions were compared across treatment arms.

After descriptive statistics were examined for the items, internal consistency of multi-item constructs was assessed with coefficient α . Next, the 176 participants were compared by treatment arm to assess for differences using Wilcoxon rank sums, Fisher's exact, and χ^2 tests. These tests were also used to

identify characteristics associated with persons withdrawing from the study. Kappa and McNemar's tests were examined to assess agreement between physicians' reports of screening and participants' self-reported screening.

The remaining multivariate analyses were conducted using SUDAAN 8.0.1 Software for the Statistical Analysis of Correlated Data (Research Triangle Institute, 2002) to account for the correlated data resulting from repeated measurements and including persons from the same family. The data file contained multiple records per person with an indicator for time and family membership (based on index patient). Adherence (yes/no) was modeled as a logistic regression with variance estimation and robust SEs calculated using DESIGN = WR, which is similar to the generalized estimating equation approach of Liang and Zeger (41). The model was tested with treatment group, time, and treatment by time interaction. Cross-sectional models examined 4- and 12-month adherence excluding those who were adherent at the baseline assessment. A variable "family" (i.e., more than one family member participating) was added to the cross-sectional models to test whether having a family "cluster" in the trial had an effect on intervention outcome. In sensitivity analyses, conducted to test the effect of attrition, the same models were run with missing adherence data imputed using the last observation carried forward.

Secondary health behavior outcomes were tested in a similar manner with either logistic or multiple regression depending on the variable. These included alcohol consumption, smoking, skin self-exam, fruit and vegetable intake, and moderate and strenuous physical activity.

Mediator analyses were conducted using the approach described by Baron and Kenny (42) and MacKinnon et al. (43), applying SUDAAN regression models to account for correlated data due to multiple family member participants. The hypothesized mediators included 15 scales or subscales, including barriers, knowledge, controllability of cancer, accurate risk perception, and moderate levels of worry. For those variables significantly related to treatment, the mediator and treatment were used to predict adherence to examine mediation effects in individual models.

Results

Participant Characteristics, Treatment Group Equivalence, and Attrition. The current analyses focus on the 176 persons who received the intervention counseling session. Because families participated in this study, members within families were assigned to the same treatment arm to reduce the possibility of contamination of treatment effects. Among our sample, there were 108 different families, with a range of one to six persons per family participating [$X = 2.3$ (1.2); median, 1]. Sixty-three percent of participants had at least one other FDR who received an intervention (CCRC or GHC). The distribution of family size did not differ by treatment arm. For each treatment arm, there were almost equal distributions of the FDR being a child of the index patient or a sibling (at least 49.4% for each).

Participating FDRs had an average age of 54.4 (SD, 11.5); 62.5% were female and most were of Japanese ethnicity. Nearly half were college educated. Nearly all FDRs had health insurance and an identified personal physician. Treatment arms did not differ on index patient gender and disease characteristics, on FDR demographics, on primary and secondary outcomes (Table 1), or on health behaviors and attitudes (data not shown). Compared with decliners and those who could not be reached, the FDRs who participated were more likely to be children of index patients and younger.

Attrition analyses compared the 28 persons who withdrew before the intervention to the 176 who received it. Of those who received the intervention, 93.2% ($n = 164$) completed the

Table 1. Baseline characteristics of participants who attended a counseling session

Characteristic	Total*	Intervention	Control
Index patient	(n = 108)	(n = 54)	(n = 54)
Gender (% female)	41.6	50.0	44.9
Age at diagnosis [mean (SD); range, 42-83]	66.5 (10.6)	65.1 (10.6)	67.9 (10.6)
Stage at diagnosis (% local)	60.8	58.3	63.3
FDRs	(n = 176)	(n = 85)	(n = 91)
Age [mean (SD); range, 40-86]	54.4 (11.5)	52.9 (10.5)	55.8 (12.2)
Gender (% females)	62.5	65.9	59.3
Ethnicity			
% Japanese	57.4	52.9	61.5
% Hawaiian or part Hawaiian	14.2	16.5	12.1
% Caucasian	11.4	15.3	7.7
% Other (Filipino, Chinese, Hispanic, Korean, mixed)	17.0	15.3	18.7
Marital status (% married or living together)	73.6	73.8	73.3
Education (% college graduates)	45.1	46.4	43.8
Household income (% \$50K or higher)	59.5	60.2	58.8
Religious affiliation (% Catholic or Protestant)	47.1	56.6	37.9
% Having health insurance	98.3	97.7	98.9
% With a regular source of health care	90.9	88.2	93.3
CRC-related symptoms in past 6 mo (% with 1 or more)	26.7	31.8	22.0
% History of bowel disorder (IBS, ulcerative colitis, diverticular disease, or polyps)	25.6	21.2	29.7
Risk			
% Level 1	56.3	56.5	56.0
% Level 2	17.0	12.9	20.9
% Level 3	26.7	30.6	23.1
Recommended screening level			
FOBT	21.6	25.9	17.6
Flexible sigmoidoscopy	46.0	38.8	52.8
Colonoscopy	32.4	35.3	29.7
Adherence to CRC screening recommendation	30.1	29.4	30.8

NOTE: No differences were found between groups.

Abbreviations: CRC, colorectal cancer; IBS, irritable bowel syndrome; FOBT, fecal occult blood testing.

*Sample sizes smaller for some items due to missing data.

study. We also compared the 12 persons who withdrew after the intervention with the 164 who completed the study. Although there were some trends related to sociodemographic characteristics and psychosocial variables, early withdrawal from the study was not related to treatment arm.

Main Effects Analysis. Main effects analysis for colorectal cancer screening adherence was tested by the treatment-by-time interaction using all measurements: baseline and 4- and 12-month follow-up data. The overall interaction contrast was marginally significant ($P = 0.09$), whereas the specific 4-month follow-up variable was significant ($P = 0.03$), indicating a significant treatment effect at the 4-month evaluation that was not present at the 12-month follow-up (see Fig. 2 and Table 2). The net change for the CCRC group (above the GHC increase) was a 13 percentage point increase in adherence at 4 months, which was reduced to 11 points at 12-month follow-up. Two

cross-sectional models, looking only at participants not adherent at baseline, were run to further examine the 4- and 12-month effects. The 4-month follow-up clearly shows a significant treatment effect ($P = 0.03$) for the intervention (see Fig. 3 and Table 2), with the net increase being a 17 percentage point increase. The 12-month model showed a nonsignificant trend with a net 14 percentage point increase. The interaction of family (more than one FDR participating) by treatment group was not significant.

Sensitivity analyses were conducted for the above three models on all enrolled/randomized participants and all participants receiving the intervention, using the last observation carried forward if adherence data were missing, to see how our results differed from an intention-to-treat model. For the models using all time points, the main effect seemed slightly attenuated for the interaction term ($P = 0.16$ and 0.13) for the enrolled/randomized and treated participants, respectively. The 4-month follow-up cross-sectional models showed mixed differences with the enrolled/randomized model being comparable ($P = 0.02$) and the treated subgroup having a slightly attenuated effect ($P = 0.05$).

Main effects analyses for other behavioral outcomes were also tested by the treatment by time interaction using all measurements. Unfortunately, there were ~34% missing at the 4-month follow-up because these outcomes were not asked due to a procedural error. Although fruit and vegetable intake were reportedly increased at 4-month follow-up and recent skin self-exam was more likely to have occurred by 12-month follow-up, these findings were unrelated to treatment condition. Physical activity showed a significant treatment by time interaction, but only the 4-month follow-up variable was significant (and not 12-month follow-up variable), and showed a drop in activity for CCRC participants at that assessment. A marginally significant interaction was found for smoking, which was due to a significant 4-month follow-up variable, showing fewer smokers for CCRC at 4 months [odds ratio

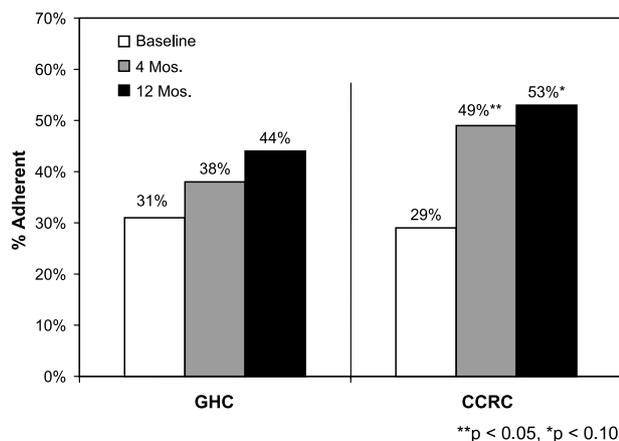


Figure 2. Change in adherence after CCRC.

Table 2. Main effect models for colorectal cancer screening adherence and other outcomes

	GHC (n = 91)	CCRC (n = 85)
Model 1: all participants, all assessments*		
Baseline		
Odds ratio (95% confidence interval)	1.00	0.94 (0.50-1.75)
Adjusted proportion (SE)	0.31 (0.04)	0.29 (0.05)
Month 4		
Odds ratio (95% confidence interval)	1.40 (1.11-1.77)	2.14 (1.11-4.12)
Adjusted proportion (SE)	0.38 (0.05)	0.49 (0.06)
Month 12		
Odds ratio (95% confidence interval)	1.79 (1.31-2.45)	2.52 (1.31-4.86)
Adjusted proportion (SE)	0.44 (0.05)	0.53 (0.06)
Model 2: participants not adherent at baseline, 4-mo follow-up †		
Odds ratio (95% confidence interval)	1.00	3.08 (1.13-8.35)
Adjusted proportion (SE)	0.11 (0.04)	0.28 (0.07)

**P* < 0.10 for interaction term.†*P* < 0.05.

(95% confidence interval), 3.30 (1.12-9.74)]. No effects were found for self-reported fat intake and alcohol consumption.

Mediator Analyses. Mediator analyses were conducted based on the 4-month follow-up assessment. Model 2 presented in Table 2 established the significant effect on change in adherence at the 4-month assessment. Next, the individual mediators were tested for treatment effects. Only 3 of 15 potential mediators showed change related to treatment group: knowledge, general knowledge (subscale), and perceived risk (simple change score). Perceived risk increased in the treatment group (CCRC adjusted mean change score, 0.48; GHC, 0.01). The final test of mediation requires that the mediating variable is a significant predictor of the outcome when tested with treatment in the model and that the treatment effect is attenuated with the addition of the mediation variable. None of the three mediators was significant predictors of adherence.

Reactions to the Interventions. Participant reactions to both CCRC and GHC interventions were consistently high, with no significant differences between groups on helpfulness of the tailored print materials (4.7 ± 0.66 for CCRC versus 4.5 ± 0.77 for GHC) or ratings of the nurse/health educators (4.8 ± 0.43 for both groups). The CCRC intervention was rated higher for the amount of new information learned (4.3 ± 0.90 for CCRC versus 3.8 ± 0.95 for GHC; *P* < 0.001) and for usefulness of the information (4.7 ± 0.60 for CCRC versus 4.5 ± 0.77 for GHC; *P* < 0.05).

Discussion

The CCRC as conducted in the FACETS Project was effective in increasing adherence to colorectal cancer screening in FDRs 4 months after the intervention compared with an attention-matched and tailored GHC intervention. The net changes due to the CCRC intervention after 4 months were 11 percentage points for all participants and 17 percentage points when the analysis included only the 66.5% who were nonadherent at baseline. The CCRC intervention led to a short-term decrease in physical activity.

The use of an attention-matched and tailored control group put the CCRC intervention to a difficult test. The smaller-than-

planned sample size also meant that a large effect size was needed to reach statistical significance.

Our CCRC intervention was a multicomponent intervention that communicated colorectal cancer risk in several formats (face-to-face counseling, printed materials, and telephone follow-up), with personal information, and in conjunction with tailored barriers analysis and tools to encourage specific action steps. This type of intervention could be integrated into primary care settings where a family cancer history is part of routine health assessments. Future research should test the effectiveness of the CCRC intervention in such real-world settings.

Family-oriented interventions have unique potential to capitalize on targeting family clusters by inviting multiple relatives of a cancer patient to take part in a "family risk counseling" session. In our study, 63% of participants had another family member in the study, but fewer than half of those participated in joint counseling sessions. Thus, we could not test the question of whether CCRC might be more effective with multiple family members being counseled together. At the same time, as our experience suggests, it may not be realistic to expect adult relatives in intermediate-risk families to arrange their schedules for group cancer education or counseling.

We also examined the participation data and found that, in families with more FDRs referred for possible participation, there was a lower participation rate (65%) than for families with only one FDR referred (72% participation). There was one exception, a family with seven persons of whom six participated. Our interpretation of this analysis is that there is a difference but it is not striking. Additional family-based recruitment approaches might have yielded more participation, but due to respect for individuals' privacy and to avoid any appearance of coercion, these were not attempted.

Limitations. Our accrual rates were well below what we projected for a variety of reasons affecting eligibility as well as a high rate of refusal to participate. Most of the refusals were simple refusals to take part in an interview, with ~20% reflecting unwillingness to give FDR information or to return family tree information (24). This suggests that a population-based approach, although theoretically strength for a study of this nature, may not be an efficient approach to accrual. We also attribute this experience at least partly to the nature of the disease we are addressing and a persistent unwillingness to discuss colorectal cancer in families (25). Although there is

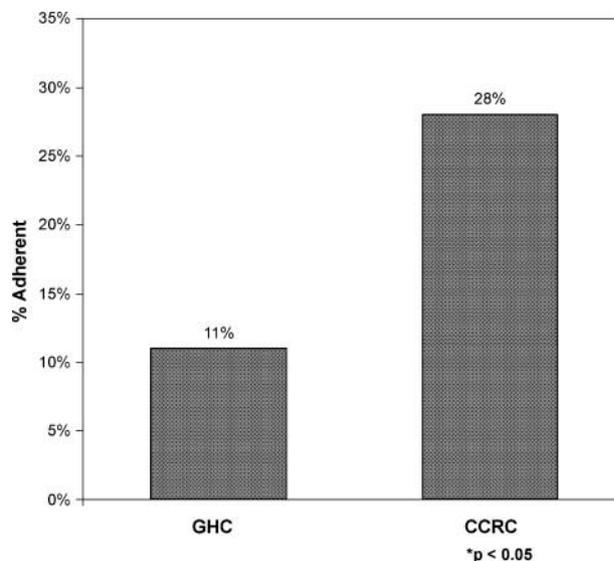


Figure 3. Intervention effects at 4 mo for participants not adherent at baseline.

much more public information about colorectal cancer screening now than when this study began, the disease is still not much discussed.

The sample in this study was well educated and most had health insurance, so the findings may not apply to those who lack resources. In addition, the follow-up period was only 12 months, which might not capture adherence to screening by flexible sigmoidoscopy or colonoscopy that has longer recommended intervals. However, we expect that any intervention effects would occur within 1 year if participants were out of compliance at baseline so this is not a major concern.

Conclusion

The FACETS study tested a CCRC intervention for relatives of persons diagnosed with colorectal cancer, and found significant effect of CCRC at 4 months after intervention, and especially for those who were nonadherent at baseline. We thus interpret these findings as highly encouraging and would recommend adaptation of the CCRC for use with relatives of colorectal cancer patients in other settings. There is a need for practical, effective interventions to encourage screening in populations at risk, and the findings of the FACETS study support the efficacy of a culturally targeted risk counseling intervention.

Acknowledgments

We thank Regina Suyderhoud, Tiffany Hurt, Leslie Welsh, Nancy Rosales, Lori Wachi, Sally Vernon, Caryn Lerman, Loic Le Marchand, the staff of the Hawaii Tumor Registry, Greigh Hirata, Tammy Stumbaugh, and all the participating families.

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