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A Randomized Controlled Trial to Motivate Worksite Fecal Occult Blood Testing

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Colorectal cancer is second only to lung cancer as a cause of cancer death in the United States. Studies have shown that fecal occult blood (FOB) tests are effective in detecting colorectal cancer in its early stages. To increase the participation in the FOB test among the working population, a randomized controlled trial was conducted. A total 278 federal employees 40 years or older in Washington State were randomly divided into a intervention group which received a Colorectal Cancer Risk Appraisal and a control group which received a simple information letter. After three months a follow-up questionnaire was sent to all participants to measure the effectiveness of the intervention. As a result of the study, the intervention group had a 4.3% highter compliance rate with the FOB test during the three month follow-up period($p=.10$).

The largest effect of the intervention was on the employees' intention to get a FOB test within the next year (62.6% in the intervention group vs. 36.2% in the control group, $OR=3.18$, $p<.001$).

Key Words: Worksite cancer prevention, hemoccult test, cancer risk appraisal

Cancer is the second leading cause of death in the United States, and colorectal cancer ranks second to lung cancer as the leading cause of cancer deaths. It also ranks second to lung cancer in cancer incidence. The National Cancer Institute(1987) reported that if colorectal cancer is detected at an early stage, survival can be increased substantially. While only 6% of cases diagnosed with colon cancer at an advanced stage survive 5 years following diagnosis, 87% of those diagnosed at a localized stage are alive after 5 years. For rectal cancer, there is only a 3% 5-year survival for cases diagnosed at the advanced stage; yet, the 5-year survival for cases diagnosed at a localized stage is 81%. Although both comparisons could be explained in part by lead time bias or by length-biased sampling of cases(Miller *et al.* 1983; Morrison *et al.* 1985), these statistics suggest that early detection could be one of the most important strategies in preventing deaths due to colorectal cancer. The American Cancer Society has suggested three methods to detect colorectal cancer at an early stage: the digital rectal examination; sigmoidoscopy; and the FOB test. Among the three screening tests, many studies (Hardcastle *et al.* 1989; Capple *et al.* 1984 ; Kewenter *et al.* 1988; Hardcastle *et al.* 1989) have evaluated and shown the effectiveness of the FOB test for early detection of colorectal cancer.

The success of the FOB test depends heavily on patient compliance with the test. Suggested methods for improving compliance derived from studies were; 1) a reminder postcard (Thompson *et al.* 1986); 2) instructions given by a nurse practitioner (Sontag *et al.* 1983); and a letter from the physician (Pye *et al.* 1988). No studies, however, have explored compliance methods in working populations. The present study examined Cancer Risk Appraisal (CRA) (adapted from Health Risk Appraisal) as a method for increasing employees' compliance with the FOB test. The CRA consists of feebdack about the individual's risk of developing colorectal cancer, based on the presence of known risk factors for this cancer, while the Health Risk Appraisal (HRA) provides an estimation of an individual's risk of dying in

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the next ten years based on health-related information (age, sex, smoking, seat belt use, etc.). Although the HRA was effective in changing several health related behaviors (Lauzon 1986; Spilman 1986), it was not specific enough to change cancer-related behaviors.

To evaluate the effectiveness of the CRA at the worksite, a randomized controlled trial was conducted in a population of federal employees. Its specific objectives were to measure the effectiveness of the intervention on whether the employees; 1) obtained a FOB test during a three month follow-up periold; 2) changed their colorectal cancer-related beliefs and knowledge about the availability of the test through the worksite clinic; or 3) intended to get the test within the next year.

Method

Figure 1 shows a overview of the method of this study. Federal employees from three agencies in Washington State were invited to participate in the study. All 1,455 federal employees were sent the baseline questionnaire which included the colorectal cancer-related information. Among them 475(33 %) employees returned the questionnaires. This return rate was similar to those from the other studies which included about 30 to 35% of the working populations (Schenek *et al.* 1986; Paskett *et al.* in-press). Since 98% of the cases of colorectal cancer occur after age 40, 278 employees(58.5%) who were age 40 years or older were included in the study. The colorectal cancer risk levels for the 278 employees were calculated by a multiplicative model which the investigator developed for this study.

The detailed calculation methods are as follows: 1) an individual's risk factors for colorectal cancer were obtained through the baseline questionnaire; age(U. S. DHHS 1987), family history of colorectal cancer (Schottenfeld *et al.* 1982; Kahn 1984; Rozen *et al.* 1981; Love *et al.* 1984), history of Crohn's disease or Ulcerative colitis(Schottenfeld *et al.* 1982; Kahn 1984; Earnshaw *et al.* 1982; Kinlen 1982), high dietary fat consumption (Graham *et al.* 1978; Haenszel *et al.* 1973; Jain *et al.* 1980; Miller *et al.* 1983; Manousos *et al.* 1983), low dietary fiber consumption (Graham *et al.* 1978 ; Haenszel *et al.*1973 ; Manousos *et al.* 1983 ; Maisto et al 1981 ; Reddy *et al.*1983 ; Domellof *et al.*1982 ; Modan *et al.* 1975), and physical activity on the job (Garabrant *et al.* 1984 ; Vena *et al.* 1985 ; Paffenbarger *et al.* 1987) ; 2) relative risk for each of the six risk factors was multiplied to get a single composite risk score. The relative risk for each of the six risk factors was averaged from the studies or

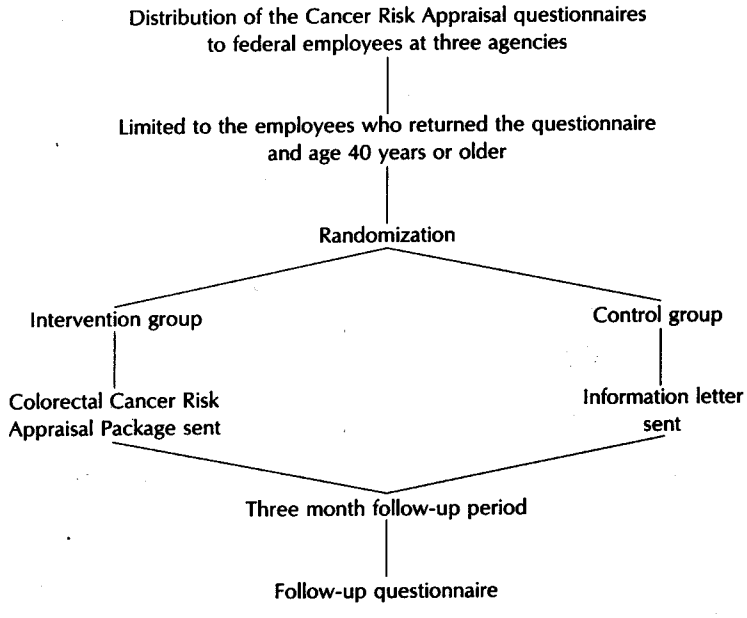

Fig. 1. *Design of the study.*

Table 1. Relative risks for the six risk factors for colorectal cancer

Risk factor		Relative risk
1. Age.	40 - 44	1.0
	45 - 49	2.0
	50 - 54	4.0
	55 - 59	6.0
	60 +	10.0
2, Ulcerative colitis	no	1.0
or crohn's disease	yes	20.0
3, Family history	no	1.0
	yes	3.0
4, Dietary fat intake	low	1.0
	medium	1.5
	high	2.0
5, Dietary fiber intake	high	1.0
	medium	1.5
	low	2.0
6, Physical activity	high	1.0
on the job	moderate	1.5
	low	2.0

sources in order to obtain the summary relative risks shown in Table 1; 3) The composite risk scores (CRS) from all study subjects were arrayed from the lowest to the highest and converted to a percentile; 4) below the 20th percentile was designated as ' normal' risk for colorectal cancer (<6 CRS), a risk score between the 20th and 62nd percentile (6<= CRS<=20) was designated as 'moderate' risk, and scores above the 62nd percentile (20<CRS) were considerd 'high' risk.

The 278 employees were randomly assigned to the intervention group or the control group using a random number table. Random assignment was stratified by whether they had a FOB test during the last three years and by three risk levels of getting colorectal cancer. The intervention group was sent the Colorectal Cancer Risk Appraisal which included two letters: the first letter listed the six risk factors for colorectal cancer along with the employee's risk of getting colorectal cancer(categrized as' normal', 'moderate', or 'high') compared to their peer group. The second letter provided some general facts about colorectal cancer including the importance of the FOB test and the availability of the test at the worksite clinic. The control group was sent only a simple letter explaining the availability of the FOB test at the worksite clinic.

Three months after the intervention was sent, a follow-up questionnaire was mailed to both the intervention group and the control group. One month after sending the follow-up questionnaire, 65.8% (n=183) of the 278 employees had returned the questionnaire. A reminder letter enclosed with another followup questionnaire was mailed to the employees who had not yet returned the questionnaire. In all, 212 employees (76.3%) returned the follow-up questionnaire; 77% in the intervention group and 75.5% in the control group.

RESULT

Comparability of the two groups

Although the study subjects were randomly assigned to the two groups, to identify possible confounding factors, the distribution of demographic characteristics, risk factors for colorectal cancer, and colorectal cancer-related beliefs, knowledge, and behavior between the intervention group and the control group were compared among the 212 employees who returned the follow-up questionnaire. The two groups had comparable demographic characteristics and smoking behavior (Table 2).

In comparison of the risk factors of colorectal cancer between the intervention group and the control group, some differences between the groups on the percentage of fat consumption and the family history of colorectal cancer were noticed. More employees in the intervention group than in the control group(10.5%) had a family history of colorectal cancer(21.5%).

This difference was statistically significant ($p<.05$). Also, there were more individuals with a low percent of fat consumption in the intervention group than in the control group. It could be hypothesized that those with a family history of colorectal cancer may comply more readily with the FOB test. Also, those who had lower fat consumption may be more health conscious people. So failure to establish a control for those factors could cause bias in measuring the effectiveness of the intervention, making the intervention group appear more compliant with the FOB test. Therefore, those two variables were allowed for in the analysis examining the effectiveness of the intervention in logistic regression and multiple linear regression models. There were no statistically significant differences between the two groups in terms of the colorecal cancer-related beliefs, knowledge, and behavior.

Evaluation of the effectiveness of the intervention

Obtaining a FOB test : The worksite clinic logs

Table 2. Distribution of demographic characteristics and smoking status of the intervention group and the control group

	Intervention (n=107)	Control (n=105)		Total (n=212)
	No.(%)	No.(%)		No.(%)
Age				
40 - 49	57(53.3)	51(48.6)		198(50.9)
50 - 59	36(33.6)	45(43.9)		81(38.2)
60 +	14(13.1)	9(8.6)		23(10.9)
	X^2= 2.40		p= .30	
Sex				
male	62(57.9)	59(56.2)		121(57.1)
female	45(42.1)	45(42.9)		90(42.5)
	X^2= .03		p= .86	
Years of education				
<=12	13(12.2)	14(13.3)		27(12.7)
13 - 16	62(57.9)	64(61.0)		126(59.4)
17 +	32(29.9)	27(25.7)		59(27.8)
	X^2= .47		p= .79	
Race				
white	98(91.6)	91(86.7)		189(89.2)
nonwhite	9(8.4)	14(13.3)		23(10.6)
	X^2= 1.33		p= .25	
Marital status				
married	80(75.5)	77(73.3)		157(74.4)
single or widowed	14(13.2)	11(10.5)		25(11.9)
seperated or divorced	12(11.3)	17(16.2)		29(46.5)
	X^2= 1.28		p= .53	
Cigarette smoking				
never smoker	46(43.0)	52(50.0)		98(46.5)
ex-smoker	47(43.9)	41(39.4)		88(41.7)
courrent smoke	6(8.4)	7(6.7)		16(7.6)
unknown	5(4.7)	4(3.9)		9(4.3)
	X^2= 1.10		p= .78	

for the follow-up period(Oct., Nov., and Dec., 1988) were reviewed for participation in the test. Since the worksite clinic logs are available on all subjects, including those who did not return the follow-up questionnaire, the analysis was based on all 278 employees who were randomized at the beginning of the study (139 intervetion cases and 139 control cases). Twelve employees (8.6%) in the intervention group and 6 employees (4.3%) in the control group were indentified as having a FOB test at the worksite clinic during the three month follow-up period. The odds of having the test in the worksite clinic were 2.32 times greater in the intervention group than in the control group after allowing for percent fat consumption and family history of colorectal cancer. This finding was marginally significant (p=.10).

Colorectal Cancer-related beliefs and knowledge : To evaluate the effectiveness of the intervention on the employees' colorectal cancer-related beliefs and knowledge, perceived susceptibility to colorectal cancer, perceived benefit of the FOB test, and knowledge about the FOB test were examined. The differences between the two groups in those variables were not statistically significant.

Intention of getting a FOB test within the next year : Intention has been studied as a strong predictor of the actual behavior using the Fishbein model (Fishbein & Ajzen 1975; Ajzen & Fishbein 1980). As another way of measuring the effectiveness of the intervention on the participation in the test, an individual's intention of getting the test

Table 3. Logistic regression model to predict the intention of getting the FOB test within the next year

Variables	Odds ratio	95% C.I.
group (0= control, 1= intervention)	3.65	(1.96 - 6.81)
'moderate' risk (0= no, 1= yes)	2.53	(1.00 - 6.43)
'high' risk (0= no, 1= yes)	3.98	(1.53 - 10.37)
Knowledge about the FOB test availbility at the worksite clinic (0= no, 1= Yes)	2.10	(1.10 - 4.00)
Participated in the FOB test during the last three years (0= no, 1= yes)	1.96	(0.97 - 3.98)

within the next year was analyzed. In this analysis, a significantly higher number of individuals in the intervention group indicated that they intended to get the test than those in the control group. The odds of intending to getting a FOB test within the next years in the intervention group was 3.18 times greater than in the control group. Even after adjusting for confounding factors(% fat concumption and family history of colorectal cancer), the odds ratio for this association was statistically significant($p < .001$). Stratified analysis and logistic regression were done to examine effect modification with the following variables: age, sex, education, race, marital status, subjective risk level at baseline, objective risk level, knowledge about the availability at the worksite clinic at baseline, participation in the test during the last three years, and smoking status. However, none of the beta coefficients of the interaction terms in the logistic regression model was statistically significant. Therefore, none was considered to be a significant effect modifier.

To develop the best predicted multivariate model for the intention of getting the test within the next year, a logistic regression model was developed. As a result, the best model (Table 3) included the following variables: intervention group(OR=3.65, 95 %, CI=1.96-6.81), moderate risk group (OR=2.53, 95% CI=1.00-6.43), high risk group (OR=3.98, 95 % CI=1.53-10.37), knowledge about the abailability of the FOB test at the worksite (OR=2.10, 95% CI=1.10-4.00), and participation in the FOB test during the last three years (OR=1.96, 95% CI=0. 97-3.98). In summary, individuals who were more likely to have intentions to get a FOB test within the next year were as follows: in the intervention group, at 'moderate' or 'high' objective risk of colorectal cancer, aware of availability of the test at the worksite clinic, and had done the FOB test during the last three years.

DISCUSSION

The success of the FOB test depends heavily on an individual's compliance with the test. To increase the compliance with the FOB test, three methods(Thompson et al. 1986; Sontag et al. 1983; Pye et al. 1988) have been identified in clinic populations. However, there have been no studies available to evaluate the methods for increasing compliance with the FOB test in a working population. The present study developed a Colorectal Cancer Risk Appraisal package, which was adapted from the Health Risk Appraisal, as a intervention strategy to increase compliance with the FOB test in a working population.

The only available study using the idea of Cancer Risk Appraisal(CRA) was the Taplin, et al study (1989). The subjects of their study were 2, 422 female enrollees in Group Health Cooperative who were invited for screening because they were at ' high' or 'moderate' risk for breast cancer. They found that the high-risk group showed the strongest association with participation in the screening test (OR=2.59, 95% CI=2, 12-3.15) compared to the moderate risk group. Among many differences between the present study and the Taplin study, the followings are distinct differences: study design(ran-

domized vs. descriptive); study population(working population vs. GHC enrollees); cancer site(colorectal vs. breast); cancer risk calculation(multiplicative model vs. risk algorythm). Due to the many different aspects between the two studies, direct comparison of compliance rates with the outcome variable was not a meaningul.

There are couple of strengths in the present study. First, a randomized controlled trial, which is a more powerful experimental design than a quasi experimental design or a descriptive study design, was used for this study. In a randomized controlled trial, intervention and control groups differ from one another only by chance, so that whatever processes may be competing with the treatment to produce the measured outcomes are present in the intervention and control group to the same extent, except for chance fluctuations(Rossi & freeman 1985). Studies have shown effective methods to motivate compliance with the FOB test for hospital outpatients. However, those methods are not applicable to working populations. One strength of the present study was an evaluation of a method for increasing the compliance with the FOB test for a working population. Thus, the results of this study can be applied or modified to colorectal cancer prevention programs in working populations. For the first time, the concept of Cancer Risk Appraisal was applied to a working population.

The results of this study shows some evidence that the Cancer Risk Appraisal can be used as a cancer prevention strategy for working populations.

There are some limitations in this study such as unproven validity of CRA and lack of generalizability. It could be hypothesized that individuals who are at high risk of colorectal cancer may participate more in the FOB test. The data showed strong association($p<.005$) between the risk status and the participation in the FOB test during the last three years at the baseline questionnaire. Also, it could be hypothesized that individuals who are at high risk of colorectal cancer perceived themselves to at high risk of colorectal cancer. The analysis indicated significant association(Pearson correlation = .23, $p<.005$) between the risk status and the perceived risk status at the baseline questionnaire. The above analysis suggested some eviedence for the validity of the Colorectal Cancer Risk Appraisal, but since this study applied the CRA concept as a pioneer method, more studies are needed to test the validity of the CRA.

It is conceivable that federal employees are more health-motivated and more educated than the general population or private sector employees. For example, the participation rate in the FOB test during the last three years (64.7%) in these study subjects was much higher than in surveys conducted by others. A survey done by the American Cancer Society found that 44% of persons age 40 years or older ever had a FOB test (1983). The Gallup survery (Ericksen 1986) found that 42% of adults were aware of the FOB test, 20% having taken the test at least once. Lastly, according to National Health Interview Survey done in 1987, more than 60% of men and women, 40 years or older, had never had an FOB test. Persons in this study also had higher educational levels than employees from some other studies. Forty-four percent of employees from Schenek's study (1986) and 72% of employees from Paskett's study (in-press) had post high school education, whereas 85.3% of the employees in the present study had post high school education. Therefore, the information from this study using federal employees might not be generalized to the other private sector employees who might have different charcateristics.

Finally, there are several suggestions for further studies. In this study, individuals in the intervention group showed significantly greater intention to get a FOB test within the next year than those in the control group. It would be interesting to follow-up these individuals in the near future to determine whether they actually get a FOB test. Since the intervention was more effective than a simple letter about the FOB test in increasing the participation in the FOB test at the worksite clinic and changing the employees' intention to get a FOB test within the next year, a replicate study using the Colorectal Cancer Risk Appraisal package as an intervention strategy for a colorectal cnacer prevention program is suggested for other working populations. As already mentioned in the limitation section, because of unknown validity of the CRA, studies are suggested to test the validity of the CRA. A case-control study using cases with colorectal cancer and controls without colorectal concer is an example. After collecting the risk information of colorectal cancer, it can be tested whether the risk status of colorectal cancer which was used in the present study can differentiate the cases and the controls using logistic regression analysis.

One of the most frequent reasons for not obtaining a FOB test during the follow-up period in individuals age 50 years or older was 'that it was not recommended by doctors'. A survey done by Shapiro and Associates (ACS 1983) indicated that many

interviewees did not perceive tests for the detection of colorectal cancer to be part of a routine physical examination. Since the FOB test can be done easily during an annual physical examination, education of primary care physicians may contribute to increasing the participation rate in the FOB test. Also, according to the present study, 31.3% of the nonparticipants in the FOB test had misconceptions about the test: 'didn't know that I should'(15.2%), ' did not know the test existed'(2%), 'cost too much' (2%), 'I see no reason for it'(6.1%), 'I don't know what this is'(3%), and 'might cause pain'(3%). These data suggest that educational programs for working populations may be needed to help change employees' knowledge and misconceptions about the FOB test.

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