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Home-administered fecal occult blood test for colorectal cancer screening among worksites in Taiwan

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Abstract

Background. This study assessed the perceived acceptance, difficulty level, and screening efficacy of home-administered fecal occult blood test (FOBT) among a Chinese population.

Methods. Participants (age 40 and above) were recruited at various worksites in Taiwan during the summer of 2002. A single group pretest and posttest design was used.

Results. The 1-month follow up rate was 81% (304/375). Screening result return rate (76%) and FOBT completion rate (74%) using the home-administered kit (HAK) were both high. Intention towards FOBT in the coming year significantly increased after the intervention ($P < 0.001$). At pretest, participants demonstrated higher perceived acceptance and screening completion efficacy of FOBT using home-administered kit (HAK) than the traditional method ($P < 0.001$). At posttest, the perceived difficulty of FOBT using HAK was significantly lower than the traditional stool-collecting method ($P < 0.001$). While the acceptance of HAK remained high both before and after the intervention, the acceptance and screening efficacy towards traditional FOBT decreased significantly ($P < 0.001$).

Conclusions. This study showed the great potential of using home-administered FOBT to promote colorectal cancer (CRC) screening among a Chinese population. Future intervention using innovative screening strategies will need to consider the participant's stage of adoption and cultural beliefs related to screening and preventive behaviors.
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Keywords: FOBT; Home-administered kit; Cancer screening; Worksite; Chinese; Taiwan

Introduction

Colorectal cancer (CRC) is the number three cancer killer for both men and women in Taiwan [1]. However, it is one of the most detectable forms of cancer, also one of the most treatable forms, if detected early. The 5-year survival rate for early stage CRC is greater than 90%. Thus, early detection of colorectal cancer is very important in decreasing mortality from this cancer.

There is increasing scientific evidence to support the effectiveness of population-based screening with fecal occult blood test (FOBT) and flexible sigmoidoscopy (FS) in reducing deaths from colorectal cancer through early detection [2–7]. The American Cancer Society recommends that men and women above 50 obtain an FOBT every year and an FS every 5 years.

Despite the proven efficacy of CRC screening, the 1997 Behavioral Risk Factor Surveillance Survey (BRFSS) findings suggested that screening utilization is fairly low. Only 19.8% of the respondents aged above 50 years reported having undergone an FOBT during the preceding year, and 30.5% reported a sigmoidoscopy within the past 5 years. Asian-Pacific Islanders (API) reported even lower screening utilization, with a rate of 11.5% for FOBT and 25.9% for sigmoidoscopy [8].

Although FOBT using home-administered kits (HAK) has gained some popularity in the United States, it has not reached the Chinese population in Taiwan. These home-administered kits have been proven clinically to be safe and accurate by FDA in the US.

The purpose of this study was to obtain initial reactions and feedbacks from a sample of Chinese people in Taiwan concerning the use of a home-administered kit (called "EZ

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DETECT") for FOBT screening. Specifically, this study assessed screening completion rate and screening intention. This study also assessed and compared the perceived acceptance, screening efficacy, and perceived difficulty level of using the self-administered screening method and traditional FOBT screening approach.

The National Health Insurance Plan in Taiwan provides health care coverage for every citizen. Adult citizens age 40 and above in Taiwan are eligible for a routine health exam every 3 years that includes an FOBT screening using traditional stool-collecting method, which requires sending a fresh stool sample to a lab or hospital for diagnosis. Currently, there are no recommended guidelines for CRC screening in Taiwan. There are also no mass colorectal cancer screening programs or any home-administered kits available in Taiwan. This study served as an important initial attempt to understand FOBT screening using a self-administered approach for this population. The convenient and sanitary home-administered kit used in this study may provide new opportunity to promote FOBT screening. The valuable information gained in this study can further assist the development of CRC screening promotion and education programs for the Chinese population in the future.

Methods

Study population

The study sample was selected from a convenience sample of worksites in Taiwan. To gain entry to these worksites, the researchers contacted a total of 12 worksite managers and leaders during the summer of 2002, and explained the research purpose and related issues. All the contacted worksite mangers and leaders showed interest in the study. However, two worksites did not participate because most of their employees were younger than 40 years. They were, however, kind enough to refer the researchers to other sites with more employees aged 40 and above. Managers or leaders at the eligible sites were briefed on the data collection procedures, instructions on how to use the FOBT home-administered kit, and other issues related to this study. Arrangements for data collection were then discussed and scheduled. These site mangers and leaders also helped the researchers in recruiting participants and encouraged them to participate in the study at their specific locations. Study materials were made available to all employees and their family members aged 40 or above. This research was conducted with the approval of The Committee for the Protection of Human Subjects (CPHS) at Cheng-Ching Hospital, Taichung, Taiwan.

Study procedure

This study used a single group pretest and posttest research design. Conduct of the study involved three main steps. First, study materials were distributed to the target population. The package of materials contained a consent form, pretest survey, colorectal cancer screening brochure, home-administered kit (HAK), Chinese HAK instructions, and a test result record card (in Chinese). Participants were asked to complete the consent form and pretest survey. Next, participants were asked to conduct stool tests using HAK and record their test results on the result card. Finally, after 2–4 weeks, participants were asked to return their test result cards and to complete the posttest survey.

The process of stool testing using HAK was estimated to take about 1–2 weeks, depending on an individual's bowel movement habits because three different stool samples would be needed to increase the reliability of the test result. After they completed the posttest survey, each participant was given a small gift in recognition of their participation (a travel utensil set with project logo). Doctors and nurses were available at the worksites to answer questions about test results and other study issues during the data collection hours. A health hotline from the collaborating hospital was also provided for further consultations and education. Participants who reported positive test results were followed up by health care professionals from the hospital.

Pretest of survey instrument

Before the study, qualitative interviews were conducted to ensure the appropriateness of the survey content. Participants in the qualitative interviews were recruited from community people and health care professionals. A semi-structured interview protocol with open-ended and probing questions was used to address concerns and barriers toward CRC screening. Potential behavior and environmental factors that might influence cancer-screening behavior were also explored. Appropriate revisions of the survey items were made based on feedbacks from the group ($N = 20$). The revised survey was then given to another small group of people to check readability, clarity, appearance, and content appropriateness before the formal study was conducted. These people were given a FOBT home-administered kit as a thank-you gift for their assistance.

Survey instrument

The same survey instrument with minor modifications was used for both the pre- and posttest. The final survey consisted of items on CRC screening utilization (including items about FOBT using traditional stool collecting method and HAK), demographics, and access to health care. Beliefs and knowledge related to screening were also measured. Preliminary findings showed that beliefs of cancer screening in general could significantly influence the participants' reaction towards the FOBT kit (including acceptance, self-efficacy, and intention to purchase). Detailed discussions were reported elsewhere [9].

In the "CRC screening utilization" section, previous screening utilization and intentions to have a screening in the next year were measured. In addition, we also assessed the participant's acceptance level, screening completion efficacy, and perceived difficulty toward FOBT. Descriptions of procedures for FOBT using the traditional stool collecting method and HAK method were provided in the survey. Perceived acceptance level and perceived completion efficacy level for each FOBT method were rated on a Likert scale from 1 (very low) to 5 (very high) based on the description provided.

The perceived completion efficacy using traditional FOBT was defined as the participant's perceived efficacy of collecting their fresh stool sample and returning the sample to a lab or hospital. The perceived completion efficacy for FOBT using HAK was defined as the participant's perceived efficacy of completing all three stool tests using the HAK. At the posttest (after participants had tried HAK), participants were also asked to rate their perceived difficulty levels on FOBT using the traditional vs. HAK method.

The Demographics section included items on the participant's age, gender, marital status, employment status, education level, family cancer history, perceived general health status, and perceived cancer risk during the next 5 years.

Items in the "Access to health care" section included: (1) sources of health information, (2) history of routine health check-ups, (3) previous physician recommendations regarding CRC screening, (4) previous communication with physician about CRC screening, and (5) those persons who could influence their screening decision.

Data analysis

Data on demographics and access to health care were described. Primary outcomes of the study included the FOBT screening result return rate, screening completion rate, and screening intention in the coming year. Secondary outcomes measured were acceptance level, screening completion efficacy, and perceived difficulty of FOBT using this home test kit. Non-parametric statistical analysis of Wilcoxon signed rank test was used, at pretest, to compare perceived acceptance and screening completion efficacy using the HAK and traditional FOBT screening methods. The perceived difficulty level of FOBT using HAK and traditional methods was compared at posttest. Wilcoxon signed rank tests were also used to compare the changes on FOBT intention, acceptance level, and screening efficacy before and after participants used the HAK.

All the acceptance levels were rated based on the five-point Likert scale with "very low" coded as "1" to "very high" coded as "5". Intention to have an FOBT in the next 12 months were rated from "definitely no" (1) to "definitely yes" (5).

Results

A total of 450 pretest packages including HAK were distributed to employees and their family members aged 40 and above at the 10 participating worksites on July to September 2002 in Taiwan. Among these people, 375 completed and returned their consent form and pretest survey (83%).

Demographics

The mean age of the participants was 48.18 (SD = 8.79). Most participants were married (93.3%), and about 58.8% were male. Over half of the participants had a college education or higher (54.0%), and 78.6% had a full time job. Most people (88.9%) indicated their general health condition as "fair" (39.0%) or "good" (49.9%). In terms of their perceived risk of getting cancer in the next 5 years, about 49% rated their risk as being the same as other people of their age. About 10% of the participants rated their risk of getting cancer higher than their counterparts. Almost half (49.9%) of the participants indicated that they had someone in their family who had had cancer.

Access to health care

The top three sources of health information obtained from these participants were (1) newspapers or magazines (79%), (2) TV or radio (62%), and (3) health care professionals (51.2%). About a quarter of the participants indicated that they have routine health exams (24.6%). Only 11.5% of participants reported their doctor had ever discussed the issue of CRC screening and recommended them to be screened. And 8% of participants reported they had brought this issue to their doctor's attention. Besides their doctor, the persons who had the highest influence on their cancer screening decisions were children (61%), siblings (10.7%), parents (9.3%), and spouse (8.1%).

FOBT screening rate and FOBT intention

Primary outcomes of the study were FOBT screening rate and screening intention in the coming year. At the 2–4 week follow-up, 304 of the 375 participants completed a posttest survey (81%). The screening result return rate was 76% (N = 284). Seven of the people who returned their test result cards, however, indicated that they did not complete all three stool tests. Therefore, the FOBT screening completion rate was 74% (277/375). Five people out of the 284 who returned the provided result cards had positive test results (1.8%).

Among all the study participants, 29.9% (n = 112) reported that they had had a prior FOBT. A little over half of the participants (52%) indicated that they intended to obtain an FOBT in the following year. After the interven-

Table 1
Acceptance level of FOBT using traditional stool collecting methods and home-administered kit (HAK) at pretest

	Traditional FOBT		Home-administered kit (HAK)	
	N	%	*N*	%
Very low	43	11.6	1	0.3
Low	112	30.3	5	1.3
Medium	178	48.1	93	25.0
High	23	6.2	176	47.3
Very high	14	3.8	97	26.1
Total	370	100.0	372	100.0

Note. Wilcoxon signed ranks test: $Z = -14.539$, $P = 0.000$* (HAK acceptance > traditional FOBT acceptance).

tion, Wilcoxon signed rank tests showed that the FOBT intention increased significantly ($P = 0.000$*).

Acceptance level and perceived screening efficacy of FOBT using traditional stool collecting methods vs. HAK at pretest survey

Secondary outcomes measured were FOBT screening acceptance, efficacy, and perceived difficulty. In terms of acceptance level at pretest, only 10% of participants rated the traditional FOBT as high or very high. On the other hand, 73.4% of the participants rated the HAK as high or very high. The difference was significant, indicating that the perceived acceptance was higher for the home test kit than the traditional stool collecting method at pretest ($P = 0.000$*) (Table 1).

The perceived screening efficacy using the traditional FOBT approach (return stool samples to lab or hospital) was only 22.9% as high or very high, while 82.3% of study participants perceived their screening efficacy using HAK (complete three home stool tests using the kit) as high or very high. Again, at pretest, perceived screening completion efficacy using HAK was significantly greater compared with the traditional stool collecting approach ($P = 0.000$*) (Table 2).

Table 2
Perceived screening completion efficacy of FOBT using traditional stool collecting methods and home-administered kit (pretest)

	Traditional FOBT		Home-administered kit (HAK)	
	N	%	*N*	%
Very low	43	11.6	0	0
Low	106	28.6	1	0.3
Medium	137	36.9	65	17.5
High	55	14.8	154	41.4
Very high	30	8.1	152	40.9
Total	371	100.016	372	100.0

Note. Wilcoxon signed ranks test: $Z = -14.477$, $P = 0.000$* (HAK completion efficacy > traditional FOBT completion efficacy).
FOBT screening completion efficacy with the traditional method: collect stool sample and send it back to a lab or hospital; FOBT screening completion efficacy with home-administered kit: complete three stool tests.

Table 3
Perceived difficulty level on FOBT using traditional methods and HAK (posttest)

	Traditional FOBT		Home-administered kit (HAK)	
	N	%	*N*	%
Very low	8	2.7	125	42.2
Low	32	10.7	85	28.7
Medium	111	37	69	23.3
High	122	40.7	14	4.7
Very high	27	9.0	3	1.0
Total	300	100.0	290	100

Note. Wilcoxon signed ranks test: $Z = -12.43$, $P = 0.000$*.
Traditional FOBT difficulty > HAK difficulty.

Perceived difficulty level of FOBT using HAK vs. using traditional methods at posttest

After participants had tried the kit, only 5.7% rated their perceived difficulty of the HAK as high or very high, while about 49.7% rated their perceived difficulty level of traditional FOBT as high or very high. The difference was significant, indicating that the perceived difficulty level was higher for traditional stool collecting compared with the HAK method at posttest ($P = 0.000$*) (Table 3). In general, about 92.5% of the participants reported that they prefer to use HAK if they need to do a FOBT test next time.

Changes in acceptance level before and after using HAK

The acceptance level towards traditional FOBT dropped significantly after participants tried HAK ($P = 0.000$*). The

Table 4
Changes in FOBT intention, acceptance, and perceived completion efficacy before and after try EZ DETECT home-administered kit

	Mean	SD	Posttest score − baseline score				Wilcoxon signed rank	
			Positive rank	Negative rank	Ties	Total	*Z*	*P* value
FOBT intention								
Before	3.53	0.84	104	51	144	299	−4.12	0.000*
After	3.78	0.79						
Traditional FOBT acceptance								
Before	2.60	0.91	37	117	144	298	−6.62	0.000*
After	2.19	0.87						
Traditional FOBT completion efficacy								
Before	2.79	1.1	35	119	143	297	−6.74	0.000*
After	2.33	0.98						
HAK acceptance								
Before	3.98	0.77	73	78	144	295	−0.19	0.846
After	3.96	0.87						

Note. Means were on a five-point Likert scale for intention: (1–5) = (definitely no–definitely yes).
Five-point Likert scale for acceptance and completion efficacy: (1–5) = (very low–very high).

perceived screening efficacy using the traditional FOBT approach also decreased after participants tried the home-administered kit ($P = 0.000$*). On the other hand, the acceptance of HAK remained high after people had tried the kit (Table 4).

Discussion

Overall, the study participants were relatively highly educated. Half of the participants had at least some college education. Although majority of the participants rated their health condition as good, about half of them reported they had someone in their family (family members or relatives) who had been diagnosed with cancer. Nevertheless, only less than 10% of the study participants perceived higher risk of getting cancer than the general population of their age.

This study showed a response rate of 83% (375/450) at pretest and follow-up rate of 81% (304/375). Primary outcomes of the study revealed high rates of return for screening result (76%) and completion of screening (74%). In two comprehensive review studies on CRC screening participation and adherence by Vernon and Peterson [10,11], the adherence rate to programmatic offers of FOBT, even with intensive efforts, was rarely exceed above 50%. Most of the studies reviewed used Hemoccult kit, which requires stool handling, diet restriction, and sending stool samples back for diagnosis; a procedure similar to the traditional stool collecting test method in Taiwan. Vernon and Peterson also concluded that, in general, FOBT adherence was lowest when persons were asked to pick up a test kit or to mail in a reply card to receive a kit. Those randomized trials reported near 50% FOBT screening adherence to program efforts used strategies that ranged from using a physician-signed letter along with FOBT kits in the mail out, to intensive follow-up with instructional phone calls [12–15].

The success of this study could be attributed greatly to the innovative screening strategy using the home-administered kit (HAK) called EZ DETECT. This type of HAK requires no stool handling or diet restriction. Test results can be obtained immediately through observing color changes in test tissues. The convenient, sanitary, and easy-to-use nature of the procedure gained not only high acceptance but also high screening efficacy among the participating Chinese people. Another factor that possibly contributed to the high follow-up and screening completion rate could be the great supports obtained from managers and leaders at each worksite. Although it still took a lot of effort and time in collecting data, the study did show that recruiting worksite managers and leaders as partners in the research processes could be an effective way to gain entrance and increase responses.

Although self-report is commonly used in measuring screening behaviors, there is possibility of social desirability bias. One could logically argue that population sampled from worksites might report higher screening completion due to perceived influence of supervisors. In this study, even though supervisors were asked to help in the data collection process (to encourage employees' participation), survey questionnaires and test result cards were returned directly to the researchers who were on site during the data collection period. Site supervisors were not allowed to see the response from participants, and this point was made clear on the consent form to everyone who participated in the study. The survey response rate could be higher from worksite groups than participants in other settings due to higher willingness to cooperate. However, responses to survey questions were the individual's decision. To be counted as completion of screening, participants had to not only indicate their FOBT completion at posttest survey, but also turned in their test result cards. In fact, the actual screening completion rate could be possibly higher because some participants reported completion of the FOBT screening but did not remember to bring their result cards back or did not complete the posttest survey.

Only five tests showed positive results, indicating a possibility of hidden blood in their stool samples. These persons were contacted by hospital nurses for further examination to confirm the results. A total of four participants were reached. One participant did undergo a colonoscopy for further diagnosis and did not find any suspicious polyps or lesion. The other three participants did not go through further follow-up diagnosis. Reasons mentioned including uncomfortable toward colonoscopy, perceived invasiveness of the follow-up diagnosis, no signs and symptoms, low perceived risk, and lack of time. There was not enough information for the authors to comment on the rate of positive results in the study. Since currently no mass CRC screening program existed in Taiwan, expected prevalence of positive result in this population was unknown.

The overall reported rate of ever having an FOBT screening was low (about 30%) among the study participants. The national FOBT screening adherence rate (screening in the past year) documented in the US showed that about 11.5% of Asian population adhered to the recommended guideline [8]. Further analysis from the current study also showed very similar low rate (11%) of screening adherence. For those who have ever had a FOBT, most reported they obtained it through their routine health exams. Intention towards FOBT in the coming year significantly increased after the intervention ($P = 0.000$). The result suggested the potential effectiveness of using both educational material and home-administered screening kit (environmental facilitator) as intervention strategy to promote screening.

The acceptance level and perceived screening completion efficacy of FOBT using traditional method were rated based on reading a paragraph that describes the test procedure. However, it was assumed that people in Taiwan had some experience of collecting stool samples using the traditional FOBT method. For example, it is required in Taiwan that kids in elementary schools need to collect their stool

samples to check for parasites. The procedures of collecting stool samples for FOBT and for checking for parasites were very similar. On the other hand, because none of the study participants has ever heard or used the FOBT home-administered kit, perceived acceptance level on HAK was rated based on both a description of the procedure and an actual trial of the kit.

Study results at pretest showed high acceptance and efficacy of using HAK for FOBT screening. Result showed that participants reported very low perceived difficulty of using HAK. Comments from participants addressed reasons of high acceptance toward the home test kit included: very convenient, no need to take work time off, no need to send stool samples to the hospital, easy, quick, safe, clean, and no need to handle stools.

Some interesting findings from changes before and after the intervention showed that, although this study only asked participants to try HAK, their perceived FOBT acceptance using the traditional approach actually decreased at posttest. In addition, the screening efficacy using the traditional FOBT method also decreased, while the acceptance of HAK remained high. Possible explanation could be some psychological changes influenced by comparing advantages and disadvantages of different screening experiences and expectations. Future research could further explore underlining change mechanisms. Comparison of traditional and HAK methods was done only with one sample in the current study. While the results were compelling, more authority would be gained by using a two-group design directly testing the completion rates between the two methods (i.e., quasi-experiment or controlled randomized trials).

Even though it sounds logical to introduce the proven accurate, safe, easy, clean, and more convenient FOBT screening method to promote CRC early detection in Taiwan, participant's stage of adoption needs to be considered. One of the major concerns participants expressed was the reliability and validity of the HAK. Being exposed to the new screening method for the first time, some participants did not have enough confidence towards the product. Most people in this population considered the traditional FOBT method as the "standard" approach, thus considered the traditional method providing more credible results.

A few participants also expressed their preference on an expert's opinion of the test result (i.e., let the doctor or lab technicians read the stool test results), rather than read the result themselves. Chinese people tended to see health care professionals as experts, not only in disease treatment, but also in test result interpretation. Programs using the so-called "Do-It-Yourself" (DIY) concept in cancer screening for the Chinese population will need to address this issue. Nevertheless, most participants liked the home stool test method and indicated it would be a great idea that the universal health insurance in Taiwan could cover the cost of the test kit.

In summary, by providing the home test kit along with educational brochures, this intervention showed promise for screening promotion programs in the future. The study showed high screening result return rate (76%) and high screening completion rate (74%). FOBT intention in the following year increased significantly before and after the screening program ($P = 0.000$*). Study participants reported high acceptance level, high perceived screening efficacy, and low perceived difficulty toward the innovative HAK strategy. Almost all of the participants (92.5%) indicated their preference of using the HAK if they need to do a FOBT test next time.

Some participants also suggested that, although new products or test methods may have been approved to be safe and accurate by credible government agencies (US FDA), some marketing efforts and advertisement in advance may be beneficial to increase their awareness and change their attitudes as first-time users. Endorsement from the local government on the test kit would be important as well. Furthermore, as expressed by this relatively highly educated population, some level of explanations and demonstrations of the procedure were still desired and needed even though the test procedure was considered relatively easy. Future intervention program will need to consider participant's stage of adoption when designing innovative cancer screening promotion strategies. Considerations also need to be given to issues related to different culture beliefs on cancer screening.

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